Deliverable report for

ENERI

Grant Agreement 710184

Deliverable 6.1.

Summary of empirical programme and preliminary set of indicators for e-database

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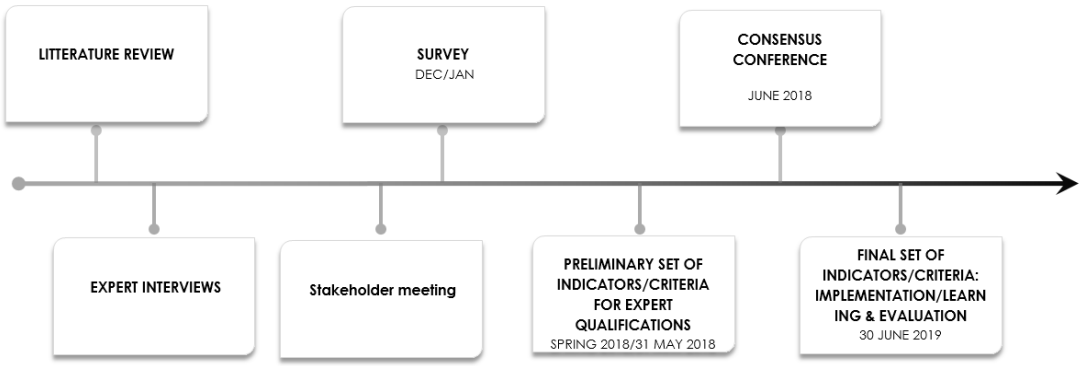
1. Description of Task at the GA

The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. Work package 6 addresses the main objective in the project "to create an e-community/database (…) of European and whenever relevant international experts in the different fields of research ethics and integrity", which "should notably ensure the certification of the knowledge level of the experts."

2. Objectives and needs of the deliverable

The main objectives are (1) to explore and develop indicators that are widely accepted in the heterogeneous field of research ethics and integrity (RE/RI) which represent expertise in the two areas to be implemented in the expert database; (2) to evaluate the experiences gained by the indicators in regards to validity and usability and to adapt them accordingly; and (3) to address the construction, mapping, and monitoring of central expert criteria.

We have created an empirical program to address the above mentioned issues in a systematic way. The first step of the program was an extensive literature review and desktop research, followed by qualitative research interviewing experts. The next phase of the program was the quantitative survey. This will be followed by a series of consensus conferences to involve potential users of the database as well as lay persons with the aim of validating our findings.



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3. Conclusions

a. Literature review

While several commissioned studies exist within the fields of RE/RI, only a few - both directly and indirectly - cover the particular issue of expert qualifications. For the objective of this deliverable, three EU projects are considered particular relevant for further review.

Commission studies for review

Proposal Call	Project Acronym	Project Title	Project Start Date	Project End Date	Sources
FP7-SCIENCE-IN-SOCIETY-2013-1	SATORI	Stakeholders Acting Together On the ethical impact assessment of Research and Innovation	01-01-2014	30-09-2017	http://satoriproject.eu/
RTD-B6-PP-00964-2013	MoRRI	MoRRI – Monitoring the Evolution and Benefits of Responsible Research and Innovation	1-07-2014	1-08-2017	http://www.technopolis-group.com/morri/
H2020-GARRI-2014-1	PRINTEGER	Promoting Integrity as an Integral Dimension of Excellence in Research	01-09-2015	01-09-2018	https://printeger.eu/

Based on the above mentioned projects as well as the literature reviewed (cf. Appendix 1[1]) Ethical Assessment Units (EAUs), the basic institutional setup for judging the ethical nature of research, are comprised of different *types* of members therefore each member needs

[1] ENERI Project 6.1. Subtask 1: Ravn et al (2017). RI/RE expert qualifications, Appendix 1 Results from the literature review, pp. 8-18.

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different skills and qualifications. The expectation is that the chairperson has a set of soft skills to swiftly manage process and team, while team members have a mixture of soft and hard skills depending on their position/function within the EAU.

In general, based on the literature and previous EU project deliverables such as SATORI,[2] the most extensive research in RE/RI EAUs to date, **experience in ethics assessment processes is valued over qualification, and training is advised for all members**. **Specific knowledge/qualification is required for "ethics specialists" and "legal experts**". A key question in reference to skills and qualifications of EAU members is the validation of such skills and qualifications. While certifications may be one potential form of validation, implementing them into projects is debated. Certifications may be offered to the process/procedure, such as once training has been provided or the person has become a member of the committee. **Regarding certification: procedure and training certification is favored over personal certification**; while there are a number of risks and problems involved in certification, it is assumed that certification in some areas of EAUs (mainly training and process) would improve trust, transparency and credibility.

b. Expert interviews

Based on the second part of our empirical program (cf. Appendix 2)[3] we have conducted a number of expert interviews[4]. All expert interviews have been conducted in September and primo October 2017; 11 interviews were performed by phone or skype and the last interview was performed face-to-face. The interviews lasted between 30-60 minutes approximately. The selection of experts/interviewees is based on an 'information oriented' selection strategy, with the aims of reaching a broad group of RE/RI experts and achieving variation according to the 'criteria of maximum variation' to then enhance in-depth understandings of potential expert criteria and qualifications. Variation has been pursued according to the following criteria: research ethics/research integrity focus; institutional category, geographical location, gender and age.

The institutional category endeavoured to include the following types of representation and experts positioned in:

[2] ENERI Project 6.1. Subtask 1: Ravn et al (2017). RI/RE expert qualifications, Appendix 1 Results from the literature review, p. 9-10.

[3] ENERI Project 6.1. Subtask 1: Ravn et al. (2017). RI/RE expert qualifications, Appendix 2 Results from a qualitative expert interview study

[4] Experts are defined based on the literature as people with deliberate practice in the field (cf. Ericsson, K. A. 2006. The influence of experience and deliberate practice on the development of superior expert performance. In K. A. Ericsson, N. Charness, P. J. Feltovich, & R. R. Hoffman (Eds.), The Cambridge handbook of expertise and expert performance (pp. 683–703). New York: Cambridge University Press)

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- National research ethics committees (REC)
- Regional/local research committees (REC)
- European network of RECs (EUREC)
- National research integrity committees/offices (RIO)
- Local/university research integrity committees/offices (RIO)
- European network of research integrity offices (ENRIO)
- National funding organization (involved in ethics review)
- European funding organization (involved in ethics review)
- Government agency (ministry)
- Industrial advisor/consultant on ethics/CSR/corporate sustainability
- Research with expertise within the field of RE
- Research with expertise within the field of RIO

Interviews have been recorded and subsequently transcribed verbatim by student assistants. All interviews have then been coded thematically in the software programme Nvivo, which allows for a transparent and comparable management and analysis of the empirical data. Interviews have been coded according to a structured coding strategy in alignment with the set of focused codes derived from the key themes explored in the interviews.

Based on these interviews, there is a broad agreement among interviewed experts concerning the value in establishing a database, which is to adopt an inclusive, diverse and transparent approach to RE/RI expertise. Different types of experts highlight different types of experience and competences in accordance with their field of expertise and RE/RI representation. Hence, ethics assessment/review competences are emphasized for ethics research project reviewers, while knowledge of integrity guidelines and codes of conduct are mentioned as important competences for journal editors, for instance. Despite variation, **similarities in core competences and skills appear somewhat consistent across different areas of expertise**. Regarding competences, the following types of acquired knowledge are suggested:

- Ethical competences (deep knowledge of national and international regulation; cases, awareness of moral dilemmas and ethical deliberation)
- Integrity competences (deep knowledge of national and international regulation, policy and guidelines)
- Research/science experience [having performed research activities in the past]
- Legal competences
- Ethics assessment/review experience [having performed ethics assessment in the past]
- Integrity assessment/review experience [having performed integrity assessment in the past]

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Experts agree on the importance of a number of skills related to communication, deliberation, collaboration and management. Below, these are summarized and grouped according to hard skills (e.g. education, technical), soft skills (e.g. communicative), process skills (e.g. administrative/management) and emotional skills (commitment, open mindedness).

Hard skills:

- Analytical skills
- Scientific skills
- Ethical commitment/thinking/abilities
- Critical thinking
- Assessment/ review

Soft skills:

- Communicational
- Interpersonal
- Eye for details
- Ability towards deliberation
- Peace-making, conflict-resolution
- Collaboration

Process skills:

- Administrative/management
- Turning ideas into recommendations/practice
- Decision-making

Emotional skills:

- Open-mindedness
- Independence
- Societal/cultural/health care awareness/impact
- Personal commitment

Regardless of RE/RI expertise type, experts interviewed emphasize and prioritize a host of emotional skills as essential for working with and within areas related to research ethics and integrity. Being open-minded towards other perspectives, as well as able to collaborate, for instance, is seen to minimize potential frictions between different discipline practices/guidelines etc. and more broadly between different (normative) perceptions of ethical/integrity standards across research fields, institutions and countries, among others.

Formal and relevant education, as well as established experience within a certain RE/RI field of expertise, counts as the most important RE/RI expert criteria. An optional training course before database entering might be relevant, but a majority of interviewees would not make it mandatory. Experts view certification as acceptable but find it difficult to see its real value and also how to incentivize issuing one.

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As an extension to our expert interviews we have included a workshop for experts on our expert stakeholder meeting in Athens to discuss these topics further[5]. Stakeholders reached consensus on the issue of certification and agreed to the advantages of issuing a personal certification for expert database membership. Expert interviewees, in turn, were much more divided in their view on the benefits of certification.

As for operationalization the inclusion of soft skills into the database of a peer-reviewed system was suggested in which, similarly to LinkedIn, other members of the database could add soft skills to any member of the database and support with evidence as to where and how this soft skill was demonstrated.

c. Quantitative expert survey[6]

A questionnaire was created in January 2018 and was distributed by the European Network of Research Integrity Offices (ENRIO) network as well as was shared at the EUREC members meeting that took place on 15th of February 2018 in Berlin. The target sample was 100 respondents and after intensive communication and repeated reminders, 125 respondents filled out the questionnaire. In selecting respondents we used non-probability sampling as randomization was not possible in order to obtain a representative sample. Following up on the expert interviews and utilizing the core expert networks of RE/RI, ENRIO and EUREC, we used expert sampling as a subset of non-probability sampling.

We contacted and utilized the membership of two main RE/RI organizations with a broad expert base and good geographic distribution:

- European network of RECs (EUREC)
- European network of research integrity offices (ENRIO)

Respondents find an international database/e-community to be a very useful initiative and name various uses from the potential use to 'find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. and 'find research ethics experts for European/international networks'. Based on the survey we may conclude that respondents value 'experience' or praxis in RE/RI assessment the most; while they also would like to see

[5] A stakeholder conference took place in Athens, September 2017 and brought together 55 different stakeholders from universities, industry, science journalism, ministries as well as project participants from several European projects on research ethics and research integrity. The conference aimed to bring together expertise from various fields and perspectives to discuss central questions as to the current and future state of RE/RI in terms of practices, infrastructures, committee compositions, among other related subjects. The conference also included a workshop on "what constitutes expertise and qualifications in RE/RI?"

[6] ENERI Project 6.1. Subtask 1: Braun et al. (2017). RI/RE expert qualifications, Appendix 2 Results from a quantitative survey

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database member experts possess some theoretical ethics/philosophy (and to a lesser extent 'legal') knowledge to back up their practical experiences.

When assessing required skills, respondents say that experts should be personally committed, *open-minded* and *impartial people*, with *analytical minds* to solve the ethical/moral dilemmas that may arise as problems. Simultaneously, they should also be able to convey and deliberate their potentially diverging opinions or point of views. Respondents suggest that the design of the database should (pre)define all skills and expertise of the database members, as well as years of practical experience, as somewhat more important than specific educational background. When it comes to specific skills and competences, respondents most value RE/RI experience as well as previous experience in RE/RI commissions, closely followed by scientific/research experience. As for the structure of the database, respondents value a selection of short self-descriptions based on key areas of expertise, rather than tick-off standardized categories or a few standardized themes and blank cells to be filled in with whatever the expert finds important. The majority of respondents claim that training should only be offered on a voluntary basis and not be made mandatory and that 'any ethics/integrity training' should be accepted as opposed to a certified training by an official body. When defining the type of certification required for the training, a majority would opt for a certification to be received following completion of the course as opposed to requiring certification of the teaching method of the specific course.

d. Preliminary set of indicators:

Database as a whole:

- Both interview experts and experts in the quantitative survey find an international database/e-community to be a very useful initiative and name various uses from the potential to 'find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. and to 'find research ethics experts for European/international networks'.
- There is a broad agreement among experts to adopt an inclusive, diverse and transparent approach to RE/RI expertise.

Database design:

- Database should
    - (pre)define all skills and expertise of the database members (but some level of co-design is accepted);

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- Contain short self-descriptions (focusing on evidence based experience) on key areas of expertise rather than tick-off standardized categories.

Database registration:

- It is advised to use a controlled (supervised and managed) approach either by an EU institution controlled registration or nomination of experts by relevant national bodies (as opposed to an open registration process based on self-registration).

Database indicator(s):
DI1: Inclusivity
DI2: Diversity
DI3: Transparency
DDI1: Definition of skills and expertise
DDI2: Description of experience

Skills and qualifications:

- Experience in ethics assessment processes (as expressed in number of years; membership in EAUs; etc.) is valued generally by experts over qualification;
- From a qualifications point of view experts are to possess:
  - Theoretical ethics/philosophy (and to a lesser extent 'legal') knowledge to back up their practical experiences;
  - Experience in
    - Scientific/research skills
    - Ethical commitment and awareness
    - Critical thinking
    - Assessment and review
  - Experience in
    - Interpersonal communication/debate

Expertise indicator(s):
EI1: Quantifiable experience in EAUs or assessement processes
EI2: Ethics/Philosophy knowledge
EI3: Specific and relevant experience in scientific research
EI4: Peer offered experience in critical thinking, ethical commitment

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Training:

- Training should be offered on a voluntary basis (especially for those with limited or no EAU experience)
- 'Any accredited ethics/integrity training' (without having defined who would provide such accreditation) should be accepted as opposed to a certified training by an official body.

Training indicator(s):
TI1: Training option (mandatory/volunteer)
TI2: Provider of training

Certification:

- Potential for
  - personal certification for expert database membership
  - personal certification for participation in training course offered

Certification indicator(s):
CI1: Certification of database membership
CI2: Certification of training participation

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4. Next steps

The **preliminary indicators** will be tested and discussed in a **series of consensus conferences**. The next phase of the program is a series of discussions or "consensus conferences" [CC] (in 4 European cities: Vienna, Athens, Aarhus, Vilnius) to discuss and debate key questions with potential database "users" and also validate our findings. The consensus conference (CC) design will follow traditional CC methodology altered to fit this particular purpose. For example, one day consensus conferences have been used to reach expert consensus in medical research. The consensus conference format attempts to reach a middle ground between a lay persons and expert participation consensus conference and invites a varied group of people who are not experts in RE/RI but are/may be stakeholders to RE/RI processes. The goal is to reach a consensus among invited stakeholders about required qualifications and certifications for EU level RE/RI expert database.

Approximately 15 stakeholders will be selected from the following potential future database "user" groups:

- People with RE/RI committee experience
- University management
- Funding agency
- Researchers
- Students
- Industry
- Science journalist
- Lay person
- Teacher (secondary school)
- Religious institution rep
- Lawyer/legal expert
- Government/local/national

Participants will receive a report on the findings of the empirical program – literature review; expert interviews; stakeholder workshop input; expert survey. Additionally, at the beginning of each CC, approx.. 15 pages will be shown as .ppt summarizing key findings and process. This will be followed by an expert Q&A and deliberation by the group.

Agreement is expected to be reached on the core set of indicators, focusing on:

- structure and particular design of individual expert profiles;
- format of registration of experts;

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- formal and relevant education, RE/RI experience;
- optional training course;
- personal certification.

Specific questions offered to the Consensus conference participants:

- *Should a broad, diverse and inclusive or a normative, limited approach to RE/RI expertise be applied? (expert types, RE/RI topics, organisational levels etc.)*

- *Should individual profiles should be highly structured and include a large number of 'tick-off' standardized categories or be semi-structured with predefined key areas/themes of expertise to be filled in with short descriptions + open categories?*

- *Should the database offer self-registration or should members be managed and monitored by a relevant EU management team and/or be nominated by relevant national governmental and institutional bodies?*

- *Should members go through a training course before being allowed to register in the database?*

- *Should individual profiles focus on years of experience within particular areas of expertise or experience need not be quantified?*

- *Should the database require personal certification of any type or such certification is not required?*

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Appendix 1.

RI/RE expert qualifications

Results from the literature review

ENERI, WP6, 6.1
2017

Tine Ravn, Robert Braun & Laura Drivdal

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1. Introduction – Ethics and integrity in research

Since the latter part of the twentieth century, developments within science and technology have progressed apace: global R&D investments in research have enlarged significantly; the number of researchers worldwide has increased by millions within the last decades and scholars are increasingly working within international and interdisciplinary research fields (IAP 2012). Moreover, scientific advances related to emerging technologies, for instance within the field of biotechnology, have brought forth significant and substantial improvements but, in chorus, they have also raised new risks and ethical questions concerning the implications for the human and non-human subjects involved (ENERI 2016).

'Innovation in natural knowledge and in its technological applications demands a corresponding capacity for social innovation' (Jasanoff 2004, 91). The quotation refers to the science-society co-productive nature of scientific knowledge and a corresponding obligation for inclusive and democratic governance. However, one could equally argue that both technological and social innovations demand amplified attention to both research ethics (i.e. moral principles embedded in research) and research integrity (i.e. professional standards of conducting research) or, taken together, efforts to foster responsible conduct of research (RCR) (Steneck 2006). As Pickersgill argues 'science today is an "ethical" business' (2012, 579) and ethical governance in relation to regulation, funding and distinct research practices constitute a growing concern in national and transnational contexts.

The issue of RE/RI has always been immersed in research processes. Nonetheless, the changing nature of science (jf. above) and of research infrastructures (i.e. funding structures, performance measures, journals, administration etc.) together with a rising number of cases of research misconduct, have resulted in a steady increase in the production of knowledge within this field. Researchers show a growing interest to understand the causes and effects of research misconduct and questionable research practices (QRP) and to conceptualise and clarify the diverse terminology related to responsible conducts of research (Anderson et al. 2013; Godecharle et al. 2014; Steneck 2006). Even so, such efforts have primarily pertained to the biomedical and behavioural sciences (Steneck 2006) and great diversity still exists in knowledge on performing responsible research across scientific fields. Similarly, while efforts to promote responsible research have resulted in global statements such as the 'Singapore Statement of Research

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Integrity'[7], a production of codes of conducts and a variety of international and national bodies to assess, oversee and reinforce responsible research practices, cross-country heterogeneity still characterise the practices, legislation, guidelines and procedures of enhancing ethics and integrity within research. Such heterogeneity also portrays efforts to handle and manage allegations of irresponsible research, however no transnational 'harmonised procedures' exist (ENERI 2016; Godecharle 2014).

A key declaration in the Singapore Statements reads that 'the value and benefits of research are vitally dependent on the integrity of research'[8] Conversely, the impact of irresponsible research conduct may be detrimental to the 'financial, political, and social support for science' (Anderson 2013, 217). Specified, adverse effects may influence research in the following four ways 1) undermine the reliability and trust in the 'research record' 2) impair the mutual trust between researchers and between researchers and the public 3) squander and misuse funds for research and 4) result in decision-making that may cause harm to individuals (researchers themselves and lay publics) (Steneck 2006; 61). Despite growing efforts to understand and document the extent of research misconduct and QRPs - of which the latter may deem worse due to its much greater prevalence (Fanelli 2009; John et al. 2012) - the nature and frequency of irresponsible research conduct is not well established (Fanelli 2009; Steneck 2006).

Several mechanisms, standards and actions are already implemented to further substantiate and foster research ethics and integrity, but as documented in the emerging literature within this field, further measures are required to address and mitigate irresponsible conduct in research (Anderson 2013; Steneck 2006). As a starting point, irresponsible conduct in research need to be addressed in terms of 'professional standards, not professional ideals' (Steneck 2006, 67) and, hence, as embedded norms integrated in scientific practices and not as mere ambition. In addition to individual, institutional and national measures to safeguard and stimulate such professional standards, transnational efforts to increase and harmonise standards are seen to benefit from professional community and network building and from knowledge exchange and the formation of knowledge bases, among other mechanisms. One way to promote such exchanges is through the setting-up of expert groups and networks whose expertise and qualified membership may add to greater awareness, dissemination, substantiation and harmonisation of cross-country knowledge, standards and 'best practices' within the fields of research ethics and research integrity.

[7] www.singaporestatement.org/statement.html
[8] preamble, www.singaporestatement.org/statement.html

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The following report constitutes a small-scale background study with the aim of identifying, reviewing and mapping potential expert qualifications/indicators. In particular, the review serves as a first step in the process 'to create an e-community/database (…) of European and whenever relevant international experts in the different fields of research ethics and integrity' (ENERI 2016, 16). Hence, the review primarily addresses the identification of central, significant and acknowledged expert qualifications and seeks to answer the following two questions:

- Based on key texts, articles and project findings, which expert indicators/criteria for involvement in RE/RI can be identified?

- What are the main forums, formats and mechanisms for incorporating and promoting ethical and integrity related concerns in research?

Due to the objective of identifying particular expert qualifications (rather than a review of the RI/RE field in general), the review will have the character of a synthesised review. The review will furthermore approach research ethics and research integrity in a collective manner as part of the definition of responsible conduct of research (RCR). Particular definitions and terminology applied will be specified in the section below.

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2. Defining the fields of research ethics and research integrity

Complete consistency in terminology and definitions within the field of RE/RI does not exist in the pertaining literature. Nonetheless, the growing body of work within these fields and, consequently, the work performed to understand and conceptualize (ir-)responsible conduct of research increasingly seem to add to a more collective and coherent nomenclature. While research ethics and research integrity often are treated as distinct research fields, they also 'combine general ethical reflections, ethics and law as academic disciplines addressing research activities, moral attitudes of researchers, normative policies of stakeholders […] and various ethical expectations of civil society' (ENERI 2016, 3). In this review, we adopt the concept of responsible conduct of research (RCR) as an overall framework that encompasses both the notion of research ethics and research integrity. A definition of RCR covers:

> 'Conducting research in ways that fulfill the professional responsibilities of researchers, as defined by their professional organizations, the institutions for which they work and, when relevant, the government and public' (Steneck 2006, 55).

Within this terminology, research integrity is defined as 'research behaviour viewed from the perspective of professional standards' and research ethics as 'research behaviour viewed from the perspective of moral principles' (Steneck 2006, 56). Research integrity comes from the Latin word *integer* and refers to the aspect of wholeness or completeness and, as encompassed within the Singapore statement, relate to the 'trustworthiness of research'. Integrity refers to research findings and the process in which they are produced (i.e. data, methods, interpretation and presentation/reporting) and whether such processes and findings meet established and appropriate scientific, legal and professional standards. By comparison, 'research ethics' pertains to the moral issues that occur in the research design and its implementation, for instance in relation to the protection of humans, animals, environment, data as well as the proper protection of other objects (Anderson et al. 2013; ENERI 2016; Steneck 2006; Strand et. al 2015).

Responsible conduct of research represents ideal research behavior on the part of individuals and institutions. Opposite, scientific misconduct constitutes the worst kind of

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research behavior and, despite definitional variation, it covers the common understanding of incorporating fabrication (data/case invention), falsification (data/results/process/equipment manipulation), and plagiarism (copying of ideas/data/results/words without crediting), (FFP) (Anderson 2013; Fanelli 2009; Steneck 2006). While ideal research behavior and scientific misconduct characterize opposites, questionable research practices (QRP) fall somewhere in between as depicted in figure 1 below. Such misbehaviors constitute a range of different practices and may represent a 'grey area' of research conduct that is difficult to determine, and often considered less serious than FFP practices.

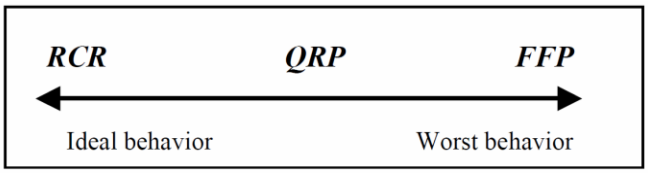

Fig. 1. Current framework for Defining Research Behaviors

(Source: Steneck 2006, 54)

Likewise, QRP are more difficult to define/conceptualize and a broad terminology is often employed. QRP may for instance be defined as 'design, analytic, or reporting practices that have been *questioned* because of the potential for the practice to be employed with the purpose of presenting biased evidence in favor of an assertion' (Banks et al. 2016, 7). Examples of QRPs include selective publishing of results/hypotheses reporting; harking ('hypothesizing after results are known); 'round-off' p-values; hide conflicts of interests; breach of confidence, among other actions (Banks et al. 2016, 8; Fanelli 2009; IAP 2012). In all instances of misconduct, the aspect of intentional deception is pivotal. Contrary, unintentional errors and interpretative/design variation are not viewed as instances of scientific misconduct (Fanelli 2009).

Responses to allegations of irresponsible research behavior differ from country to country; in some countries, national funding agencies such as the German DGF Ombudsman may act as an alternative reporting/mediator mechanism. In other countries, national bodies may function as advisory bodies only or have institutional oversight or sanctioning responsibilities. Nonetheless, in most countries the concerned university or research institution has the main responsibility for handling allegations of scientific misconduct and QRP (IAP 2012, 4).

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3. Review of empirical research on RI/RE qualifications

3.1 Introduction

The following section reviews existing material on research integrity and ethics qualifications. The first part of the section concerns a review of EC funded projects focusing on research ethics/ethic assessment and/or research integrity. The second part of the section reviews other types of material, e.g. key EU documents, research findings, institutional reports and EU network material. In this section, the review centres on qualifications related to involvement in Research Ethics Committees (RECs) and Research Integrity Offices (RIOs) and committees.

3.2 Commission studies and projects on RI/RE

While several commissioned studies exist within the fields of RE/RI, only a few - both directly and indirectly - cover the particular issue of expert qualifications. For the objective of this report, three EU projects are considered particularly relevant for further review (see table 3.2.1 below). Among these projects, the SATORI project details most specifically with expert qualifications concerning ethics committee members.

Table 3.2.1 Commission studies for review

Proposal Call	Project Acronym	Project Title	Project Start Date	Project End Date	Sources
FP7-SCIENCE-IN-SOCIETY-2013-1	SATORI	Stakeholders Acting Together On the ethical impact assessment of Research and Innovation	01-01-2014	30-09-2017	http://satoriproject.eu/
RTD-B6-PP-00964-2013	MoRRI	MoRRI – Monitoring the Evolution and Benefits of Responsible Research and Innovation	1-07-2014	1-08-2017	http://www.technopolis-group.com/morri/
H2020-	PRINTEGER	Promoting	01-09-2015	01-09-2018	https://printeger.eu/

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GARRI-2014-1		Integrity as an Integral Dimension of Excellence in Research			

SATORI - Stakeholders Acting Together On the Ethical Impact Assessment of Research and Innovation

SATORI is a 45-month long project, comprising of 17 partners from 12 countries, including an intergovernmental organisation. The aim of it is to improve respect for ethics principles and laws in research and innovation, and to make sure that they are adequately adapted to the evolution of technologies and societal concerns. The partners will develop an ethics assessment framework based on thorough analysis, commonly accepted ethical principles, participatory processes and engagement with stakeholders, including the public, in Europe and beyond.

Documents reviewed:

- D.4.1. A reasoned proposal for shared approaches to ethics assessment in the European context
- D.7.2. Exploring the potential of conformity assessment techniques to support ethics assessment
- CWA (CEN Workshop Agreement), "Ethics Assessment for Research and Innovation – Part 1: Ethics Committee".

Expertise as input for indicators/qualifications

The table collects the main aspects of needed *expertise* as observed/detailed in SATORI deliverables and the CWA (which is the basis for the standard of setting up and operating Ethics Committees on all levels of research ethics assessments).

Table 3.2.2. Examples of indicators/qualifications retrieved from SATORI

Potential indicator/qualification	**RI/RE related**	**Type of expertise** (E.g. educational,	**Organisational level of expertise** (E.g.	**Relevant scientific discipline** (yes/no/specify)	**Specific representation** (E.g. type of stakeholder, ex.

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		teaching, network etc.)	institutional, national, regional etc.)		ministry, editor etc.)
		Scientific Ethical; Administrative Research	Institutional Administrative	Yes: any scientific or technical area relevant	End user Layperson

Skills of EAU (Ethics Assessment Unit [Ethics Committee]) members

The table collects the main aspects of needed *skills* as observed/detailed in SATORI deliverables and the CWA (which is the basis for the standard of setting up and operating Ethics Committees on all levels of research ethics assessments).

Table 3.2.3. Skills of EAU

Stakeholders/members Skills required	**Chairperson**	**Secretary**	**Field Practitioners**	**Ethics Specialists**	**Experts from various disciplines**	**Institutional Representatives**	**Legal experts**	**Public representatives**
Hard skills	- technically, ethically and administratively professional - appropriate education; training and experience							
			Scientific/ technological	Ethics Religious traditions	Scientific/ technological	Competency in representing the institution	Legal	End user competency
Soft skills	Willingness to communicate Consideration of alternative perspectives Ability to evaluate benefits, risks and burdens Ability to cooperate in a group							
	Communication; Interpersonal; Problem solving;	Communication Interpersonal;						
Process skills	Administrative Ability to manage group diversity	Administrative						
Emotional skills	Open minded Impartial Personal commitment Awareness of cultural factors influencing community							
	Emotional intelligence							

Qualifications of EAU members

The table collects the main aspects of needed *qualifications* as observed/detailed in SATORI deliverables and the CWA (which is the basis for the standard of setting up and operating Ethics Committees on all levels of research ethics assessments).

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Table 3.2.4. Qualifications required from EAU members

Stakeholders/members Skills required	Chairperson	Secretary	Field Practitioners	Ethics Specialists	Experts from various disciplines	Institutional Representatives	Legal experts	Public representatives
Experience	x	x	x	x	x	x	x	x
Certification								
Training	x	x	x		x	x		
University degree in ethics/law				x			x	

- Lay persons are defined as (from a skills point of view): "persons without relevant professional expertise to better reflect the social and cultural diversity of society" (CWA p.9)
- All members should be: "technically, ethically and administratively professional"(CWA p. 13) & competent (appropriate education; training and experience) (CWA p. 13.)

Summary of skills and qualifications

EAUs are comprised of different *types* of members; therefore each member needs different skills and qualifications. In general the chairperson is required to have a set of soft skills to swiftly manage process and team, while team members should have a mixture of soft and hard skills depending on their position/function within the EAU. In general, experience in ethics assessment processes is valued over qualification, and training is advised for all members. Specific knowledge/qualification is required for "ethics specialists" and "legal experts".

Certification

Analysis of SATORI D.7.2. Exploring the potential of conformity assessment techniques to support ethics assessment pp.16-36.

A key question in reference to skills and qualifications of Ethics Committee members is the validation of such skills and qualifications. Certifications may be one potential form of validation. Need for certification is debated. Certifications may be offered to the process/procedure; the training provided or the person becoming a member of the committee.

The table presents findings of issues related to certification:

What to certify?

Certification	YES	NO
Procedure	+++	

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Training	++	
People	+	++

Potential certification of members of EAUs:

Benefits:

- Self-assessment
- Legal incentive
- Good for CV
- Improved personal marketability
- Industry benefit: quality enhancement

Hindrances:

- Hard to define "Ethics professional"
- Lack of demand and support
- Certain technological fields hard to standardize
- Varied by disciplines
- Monitoring is a problem
- Growing bureaucracy

Arguments for:

- Transparency
- Credibility
- Reliability
- Consistency
- Improvement in lack of specific qualifications
- Improvement in lack of specific education

Arguments against:

- Creating a two-class system
- Too much power to certain people
- Creating a tick-box exercise
- Different expertise needed
- EA is a citizen's issue not a professional one

Examples mentioned

- Compliance Certification Board (CCB) -- http://www.compliancecertification.org/

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Types

- Conformity assessment (CA) – as demonstration that specified requirements relating to product, process, system, person, or body are fulfilled. Certification is one of the methods of demonstrating conformity. (.D.7.2. p. 20)

Issues related to certification:

- Certification procedure based on other EU examples: Regulation (EC) 1060/2009 – Committee of European Security Regulators; Directive 2007/59/EC certificates for train drivers; Regulation No 765/2008 Accreditation and market surveillance of products.
- Revocation and withdrawal of certification
- Harmonization with other CA/certifications in the EU

Summary of issues related to certification

Need for certification is debated. In general, procedure and training certification is favoured over personal certification. There are a number of risks and problems involved, however it is agreed that certification would improve trust, transparency and credibility of EAUs.

Conclusion

A limited number of SATORI materials discuss skills, qualifications and the need for certification in ethics assessment processes. The general conclusion of the SATORI project in this regard is that "it would be premature to be too prescriptive. It should be up to the policy makers, associations of RECs and RECs (as users of the ethics assessment process) to determine (in consultation with standards and conformity assessment agencies) the best path forward." (D7.2. p. 31.) ENERI as a project does exactly this. Regarding skills and qualifications: according to SATORI findings, experience in ethics assessment processes is valued over qualification; ethics training is advised for all members. Specific knowledge/qualification is required for "ethics specialists" and "legal experts".

Regarding certification: procedure and training certification is favoured over personal certification; while there are a number of risks and problems involved in certification it is agreed that certification in some areas of EAUs (mainly training and process) would improve trust, transparency and credibility. CWA and the EA framework delivered in SATORI should/could serve as a basis for such certification.

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MoRRI - Monitoring the Evolution and Benefits of Responsible Research and Innovation

MoRRI is a service that was set up in late 2014 and lasted until spring 2018. The project's main objective is "to provide scientific evidence, data, analysis and policy intelligence to directly support Directorate General for Research and Innovation (DG-RTD) research funding activities and policy-making activities in relation to Responsible Research and Innovation (RRI)". Expected results will be disseminated through annual monitoring reports on the developments of RRI dimensions, scientific notes that will address individual RRI dimensions and a summarising policy note. Furthermore there will be reports on RRI benefits and a final report. The project will use a mix of methods such as a literature review, interviews, case studies, surveys and it will explore future trends in a visioning workshop and discuss the outcomes in a larger dissemination context.

Document reviewed:

D2.4.1. Analytical report on the dimension of research and innovation ethics

Expertise as input for indicators/qualifications

The table collects the main aspects of needed *expertise* as observed/detailed in MORRI D2.4.1.

Table 3.2.5. Examples of indicators/qualifications retrieved from MoRRI

Potential indicator/qualification	**RI/RE related**	**Type of expertise** (E.g. Educational, teaching, network etc.)	**Organisational level of expertise** (E.g. institutional, national, regional etc.)	**Relevant scientific discipline** (yes/no/specify)	**Specific re-presentation** (E.g. type of stakeholder, ex. ministry, editor etc.)
	Ethics over science awareness	Soft laws and ethical codes	Institutional/different approaches to EA ie. Representation; deliberation; efficacy of output		Diversity of members advised as participatory process requirement

Summary

The literature review of ethics in MORRI focuses on the need and process of civic or lay participation in ethics assessment and advisory processes. As a general overview, the literature review demonstrates that democratic and participatory processes may be improved and would be beneficial to the social embeddedness of ethical aspects in R&I as opposed to a "closed", "elitist", only "expert" based approach to EA (p.53; p.64; p. 73; p.84-85; p. 87; p.90). This may have a bearing on the composition of EAUs (involving laypeople

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and institutional stakeholder representatives) as well as on training and required qualification in deliberative and participatory approaches and processes.

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PRINTEGER - Promoting Integrity as an Integral Dimension of Excellence in Research

PRINTEGER is a 36 month long project (01/09/2015 – 01/09/2018), with 8 partners from 7 countries. The project aims to improve adherence to high standards of integrity in research by improving integrity policies of national and international research organisations and by providing better tools for research leaders and managers. Additionally the project will contribute by improving ethical awareness and reflection through the education of new generations of scientists with next generation educational tools.

Documents reviewed:

- D2.3 Normative analysis
- D2.4 Legal analysis
- D2.6 Scientific misconduct and integrity: An organizational perspective
- D3.1 The extent and incidence of misconduct

Main observation

The documents available are mainly conceptual clarifications and theoretical discussions preparing for the empirical studies. Related to the ENERI Task 6.1, the documents reviewed do not contain any discussions regarding certification and qualifications/skills of ethics committee members.

However, two themes in the documents reviewed indicate that the forthcoming empirical studies of the PRINTEGER project might provide relevant data/discussions for ENERI WP 6:

1. **The organisation of commissions for handling misconduct**

The document "D3.1 - The extent and incidence of misconduct" discusses how misconduct is handled at different institutions. It is highlighted that with the ambiguity over concepts, investigating and registering bodies define scientific integrity and scientific misconduct differently. The grey area of scientific misconduct is often settled informally, and hence rarely results in administrative procedures.

Further, comparing processes of handling misconduct across six countries, it is found that allegations of research misconduct are handled at different levels: responsibility can lie within the institution, with regional or national organizations, or through National Research Integrity Offices. Exactly what expertise and skills these bodies comprise is not discussed. The document is more focused on how investigating bodies handle their cases (how many misconduct notifications they register each year, the outcomes of these cases etc.). However, as expertise could be organised at different scales (institutional, regional and national), it is briefly mentioned that *'compared a system of institutional bodies, National Integrity Offices are not always qualified to investigate the allegation if misconduct, and in*

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some cases their competency is limited to providing an advice only' (p 9). From this, a simple table can be made:

Qualified to	Institutional commissions	National Integrity Offices
Investigate allegations	Yes	sometimes
Give advice	Sometimes	yes

For the ENERI task 6.1, it would have been interesting to see a further comparison of professional competences within these different investigating/registering bodies, and a comparison over general expertise (national scale) and expertise specialised into specific research fields (institutional scale). It is however unsure if PRINTEGERs forthcoming empirical studies will provide this information.

2. Forthcoming studies on how research organisations deal with integrity

Document D2.6 provides a theoretical discussion of a framework for studying the organisational responses to research misconduct, which will be applied in forthcoming empirical research. The concept of "*integrity work*" is promoted to investigate the ongoing organizational activities and strategies associated with developing, repairing and/or maintaining integrity. Three aspects are operationalized providing research questions for the empirical studies: *regulative* aspects like legislative frameworks, *normative* aspects like values and expectations, and *cognitive* aspects like culture and legitimatization. These forthcoming empirical studies aiming to provide recommendations for organizational integrity work, might deliver possible indicators for evaluating the processes of improving research integrity competences.

Conclusion

The PRINTEGER documents published so far do not discuss skills, qualifications and the need for certification in ethics assessment processes directly. This is because PRINTEGER is still in an early phase, and the empirical case studies are not yet completed. Especially two themes that will be empirically investigated in the forthcoming PRINTEGER research might provide relevant information for the ENERI WP 6: The comparison of institutional, regional and national committees across six countries, and the research on how specific organisations deal with integrity (integrity work).

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3.3 Other empirical studies, reports and material on RE/RI qualifications

Research Ethics Committees (RECs) or Ethics Assessment Units (EAUs) (see above) are key drivers for promoting ethics in research and in assessing the ethical impacts of research, emerging technologies and innovation projects. Likewise, Research Integrity Offices (RIOs) and committees play a decisive role in promoting and upholding research integrity in their capacity of advising/instructing in current guidelines/regulations and in handling cases of scientific misconduct and questionable research practices. Due to their key and prevalent tasks in promoting RE/RI, this section will gather specific information on expert qualifications related to the type of expertise required for RECs and RIOs. Other important forms of RE/RI involvement is reviewed in section 4.

Research integrity committees at the national level

While RECs seem to be more established bodies internationally, cross-country systems for approaching research integrity appear more heterogeneous (Godecharle et al. 2013; European Science Foundation 2008). According to a comparison of RI systems for handling scientific misconduct in 15 different countries, three distinct roles can be identified: a) commissions can be tasked with an advisory role b) they can have decision-making power in specific cases or c) have the mandate to 'supervise institutional processes'. A commission can be tasked with more than one of the stipulated roles (Danish Agency for Science and Higher Education 2015, 85-86). Additionally, the comparison shows that the composition of research integrity commissions vary between countries and in particular for commissions at the institutional level. For nationally established research integrity commissions, a few general characteristics of member composition can be identified:

- Members are appointed for a specific period of time, often between 2-4 years
- Members represents different research disciplines
- Members are highly acknowledged scholars
- Many national commissions have a legal expert appointed (often a judge),
- Some commissions can draw on international experts in specific cases (Danish Agency for Science and Higher Education 2015, 87)

In the revised Danish law concerning the Danish Committees for Scientific Dishonesty (DCSD), no particular collective nor individual skills and qualifications are emphasised besides from the requirement that members must be highly acknowledged scholars (Law no 383 of 26/04/2017). A review of the information provided by other national committees seems to support the observation that particular member skills and qualifications are not

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specified. Examples include The Austrian Agency for Research Integrity[9]; The German Research Ombudsman[10]; The National Commission for the Investigation of Research Misconduct in Norway[11], and the Finnish Advisory Board on Research Integrity (TENK)[12].

Research integrity committees at the institutional level

Research integrity committees and offices are increasingly being established at universities and research institutions worldwide, and procedures, strategy plans and guidelines have been produced to handle allegations of irresponsible research practices and/or advise on questions related to research integrity and ethics. As mentioned above, their composition and responsibilities may vary significantly among countries and institutions.

In the US, policies and procedures regarding misconduct in research are most often handled administratively by Research Integrity Offices or more specifically by Research Integrity Officers (RIO). The role of the RIO is not well-defined within a regulatory framework, but it often entails significant responsibilities and the functioning of being both ' prosecutor, judge, mediator, counsellor, teacher and regulatory manager' (Wright & Schneider 2010, 101). As to the collective and individual competences of RIO's, Wright & Schneider emphasizes that 'the RIO needs personal staff gifted in handling people and, ideally, staff with some training in forensics. Legal counsel, academic subject matters experts, IT experts, and a representative of institutional police or security are also key team members' (2010, 106-107).

In a study by the US Office of Research Integrity (ORI) on the 'preparedness/readiness' of US RIOs (ORI 2009), *personal characteristics* of relevance for job performance are conceptualised as:

- Behaviour: awareness about own performance and degree of satisfaction with one's own performance
- 'Degree and major field of study'
- Involvement in seeking research support
- Extent to which 'the individual has been a principal investigator on a grant'
- Length of employment
- Self-identification as a researcher (ORI 2009, 25)

In terms of *experience*, the following conceptual variables are identified:

[9] http://www.oeawi.at/en/commission.asp
[10] http://www.ombudsman-fuer-die-wissenschaft.de/?L=1
[11] https://www.etikkom.no/en/our-work/about-us/the-national-commission-for-the-investigation-of-research-misconduct/about-the-national-commission-for-the-investigation-of-research-misconduct/
[12] http://www.tenk.fi/en/members

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- Length of being an RIO
- 'Whether the RIO has ever handled any allegations, directed an inquiry, or held an investigation of alleged research misconduct'
- Conference with other RIOs or ORI employees on managing 'hypothetical' cases
- Helped produce institutional policies and procedures (ORI 2009, 25-26)

Other countries operate with institutional integrity committees and have faculty advisors appointed to instruct employees in matters concerning research integrity. At Aarhus University such advisors 'must contribute to [the] instruction on research integrity and the responsible conduct of research, as well as monitoring developments in this area'[13].

At other universities, the personal competencies of Research Integrity Advisors (RIAs) is further specified. For instance, the Australian Catholic University and the University of Adelaide specifies the following requirements for Research Integrity Advisors (RIAs):

- 'Advisors of research integrity are expected to be experienced, independent senior mentors.
- Advisors should be people with research experience, wisdom, analytical skills, empathy, knowledge of the institution's policy and management structure, and familiarity with the accepted practices in research.
- RIAs will need to be fully aware of the requirements and responsibilities for the conduct of research as outlined in the Australian Code for the Responsible Conduct of Research'[14].

Research Ethics Committees

Most countries have established research ethics committees to review and monitor research projects, and in particular within the biomedical field of research. Despite cross-country difference concerning their legislative foundation, structure and practices (ENERI 2016, 9), RECs and the role of REC members seem more similar in composition and more well-defined compared to RIOs. In the UK, around 100 research ethics committees are established as independent bodies of the Health Research Authority. A committee consists of 7-15 lay and expert members. Expert members are required to be healthcare professionals with particular professional qualifications (hard skills). However, for both types of lay and expert members, a set of essential qualities are required in order to be appointed (soft, process and emotional skills). These required skills are stipulated in table 3.3.1. below.

[13] http://www.au.dk/en/research/responsible-conduct-of-research/advisers/

[14] http://www.acu.edu.au/research/current_research_students/forms_and_policies2/policies/role_of_research_integrity_advisors; http://www.adelaide.edu.au/research-services/oreci/integrity/advisors/

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Table 3.3.1. Essential qualities required for the role of lay and expert members in NHS RECs

You should:

- have a strong personal commitment to the interests of patients who take part (or are asked to) in health care research;
- have a strong personal commitment to ensuring the highest standards for health care research;
- be able to read, understand and analyse complex issues from research proposals and weigh up conflicting opinions
- be able to take an objective stance, looking at a situation from several perspectives;
- be a good communicator with a practical approach and confidence to voice your opinions;
- be able to discuss issues with people who may not agree with you including being able to influence others from a range of backgrounds;
- be committed to the public service values of accountability, probity, openness and equality of opportunity;
- be able to demonstrate an ability to contribute to the work of the REC;
- be available monthly (approximately 10 meetings per year) with a commitment to attend at least 6 of the meetings;
- be available to undertake the review of Proportionate Review applications and substantial amendments electronically on a rota basis;
- understand the requirement for confidentiality in issues faced by a REC;
- be willing to undertake initial induction training and then at least 5 hours training per year to equip you to carry out your role;
- be IT literate and have access to a computer or tablet to allow some REC work to be carried out via email and via the Member Portal.

Source: Information for potential Research Ethics Service Committee members. Standard Application Pack all members (HRA) version 2.0, December 2015. NHS. Available at: http://www.hra.nhs.uk/documents/2015/12/standard-application-pack-rec-members.pdf

Other research ethics committees do not specify member qualities to the extent above, but state in more general terms the requirements of proper academic training and experience; expectations to collective responsibilities and to the composition of the committee (i.e. division between lay and expert, gender balance, geographical distribution). The Danish legislative basis for REC's constitutes one such example[15].

The Steering Committee on Bioethics (CDBI) of the Council of Europe has produced a 'Guide for Research Ethics Committee Members' (2010) which intends to act as an instrument for REC members within the biomedical research field. In terms of member qualities, the guidelines add to the more generic description in the section above and specifies that:

> *'REC members should have a basic understanding of the importance of research and how it can benefit human health and welfare. They should be able*

[15] Law no 593 of 14/06/2011, available at https://www.retsinformation.dk/Forms/R0710.aspx?id=137674

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> *to understand the principles of research and research methods, the research context, and the practicalities of carrying out biomedical research. They must be able to make their own independent judgements when considering the ethical issues involved in the research proposals placed before them' (Council of Europe 2010).*

As in the NHS' guidelines, the Steering Committee on Bioethics stresses the importance of initial and ongoing training of REC members.

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4 Identification of key forums/formats for practising RE/RI

The following section identifies main formats and mechanisms for incorporating and promoting ethical and integrity concerns in research. The main aim is to locate other types of involvement in RI/RE than RECs and RIOs and, if obtainable, identify existing types of RI/RE competencies, criteria, and qualifications requested at different organisational levels (e.g. institutional, national, regional) and in terms of different kinds of representation/stakeholder (e.g. committee member, ministry representative, editor etc.). These findings are assembled and presented in table 4.1 below.

Table 4.1. different types of RE/RI involvement

Type of involvement	**Type of representation** (legal experts, chair, RI officer etc.)	**Type of experience** (educational, administrative, network etc.)	**Skills required** (hard, soft, process, emotional skills)	**Organisational level of expertise** (institutional, national, regional, international)	**Scientific discipline**	**Description of skills/ expertise**	**Source(s)**
Research ethics committees at research performing organisations				institutional			D2.4.1. (MoRRi) IAP (2012)
Research ethics committees at research funding organisations			Proper skills and knowledge; sensitivity to the research context	national international			D2.4.1. (MoRRi) Economic and Social Research council (http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/our-commitment/)
Ethics Advisory Committees providing advice to governments and parliaments				national			D2.4.1. (MoRRi)
RI/RE Consultants/advisors in Ministries				national			
Consultants/advisors at European and international RI/RE organisations/ networks				international			

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(e.g. ALLEA, ENRIO, EUREC)							
Institutions governing academic integrity				National International			D2.4.1. (MoRRi)
		Involvement in national and European projects on research ethics, responsibility and integrity					
		Scientific production of articles on ethics, responsibility and integrity topics					
		Experiences with design and implementation of RE/RI training activities					
		legal/administrative RE/RI experiences (concerning open access; technology transfer/assessment etc.					
Science journalist specialized in Ehics/integrity issues							
Advisor/consultant on corporate social responsibility/ corporate sustainability							

In general, only a limited amount of resources exist that detail existing and potential expert qualifications related to involvement in research ethics and research integrity. This seems particularly to be the case in the types of RE/RI involvement that extends beyond RECs and

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RIO's. Furthermore, in terms of the material reviewed for this report, expert qualifications seem more often to be stipulated at a collective level of expertise rather than at the individual level.

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6 Further information

SATORI

Members of the EAUs[16]

EAUs consist of various types of members: a chairperson, field practitioners, ethics specialists, experts from other disciplines, institutional representatives, legal experts, public representatives and members of the public (including laypersons and end-user(s), or representative(s) of the end- user group(s) or organization(s)). The information used to develop this categorisation is contained in the ethics assessment reports within Annex 3 of SATORI Deliverable D1.1.[17]

The Chairperson
The chairperson represents the EAU in official communications and is responsible for organising and arranging the meetings of the group's members. Chairpersons are also responsible for the smooth operation of the EAU's deliberations and the timely completion and reporting of the group's decisions.

The person selected for this task should possess strong administrative competence. This competence includes the interpersonal skills in fostering productive group discussions and in ensuring that the various members of the EAU are able to contribute to the group's deliberations effectively.[18] The chairperson should also be responsible for ensuring that members receive any training they may require to fulfil their role.[19]

The Secretary
The secretary of an EAU is responsible for the administrative and bureaucratic functions of the unit. Secretaries organise the practical details of the EAU's function, such as arranging

[16] *Philip Jansen, Wessel Reijers,David Douglas, Agata Gurzawska, Alexandra Kapeller & Philip Brey, Rok Benčin, Zuzanna Warso: SATORI Deliverable D4.1* A reasoned proposal for shared approaches to ethics assessment in the European context, December, 2016, pp. 89-90.

[17] Shelley-Egan, Clare, Philip Brey, Rowena Rodrigues, David Douglas, Agata Gurzawska, Lise Bitsch, David Wright & Kush Wadhwa, *SATORI Deliverable D1.1 Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries*, June 2015. http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf ; "Comparative Analysis of Ethics Assessment Practices." *SATORI*, June 2015. http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/.

[18] Ryan, Mary Kay, "General Organization of the IRB", in Robert A. Greenwald, Mary Kay Ryan, and James E. Mulvihill (eds.), *Human Subjects Research: A Handbook for Institutional Review Boards*, Plenum Press, New York and London, 1982, pp. 29–38 [p. 32].

[19] Ibid.

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meetings, receiving proposals and distributing them to members for assessment, and acting as a point of contact between the EAU and those outside of the unit. The secretary also makes notes of EAU meetings and decisions and distributes them to members so that there is a record of their deliberations.

Like the chairperson, the person selected to be the secretary should possess strong administrative competence. Good communication skills assist the chairperson in assuring researchers that the EAU's procedures are clear and unbiased. Similarly, the chairperson's communication skills contribute to explaining and justifying the EAU's decisions to researchers in a respectful manner. Good record keeping of the EAU's deliberations and decisions will assist in achieving these goals.

Field practitioners
Field practitioners possess expertise relevant to the R&I activity the EAU reviews. The specific expertise is often connected with the role of the institution associated with the EAU. For example, physicians, pharmacists, and nurses may belong to a hospital EAU.

Ethics specialists
Ethical specialists have expertise in evaluating moral issues and who are sought after for moral advice. This category includes religious leaders or representatives as well as ethicists and philosophers.

Experts from other disciplines
Sometimes practitioners and experts from fields not directly related to the work under review are included in an EAU. They serve a similar function to lay persons on EAUs in that they bring an outside perspective (i.e. one from outside the particular R&I field) to the EAU's assessment. Unlike lay persons, however, experts from other disciplines are included primarily for their professional expertise that is *indirectly* relevant to the R&I activity being assessed. For example, sociologists may belong to a medical ethics committee to provide expertise on the relevant social factors associated with medicine and medical care.

Institutional representatives
Members of the institution associated with the ethics assessor are also common members. For example, university EAUs may include faculty members, administrative staff, PhD candidates, and student representatives.

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Legal experts

Lawyers and those with legal expertise are valuable for ensuring that the work reviewed by an EAU meets any legal requirements and legislation that affect it. Including legal experts is important for protecting the legal rights of human participants and for complying with the regulations concerning animal experimentations and other biological research. Legal expertise also helps to identify legal problems that might arise for the researchers and their institution if particular R&I activity is performed which does not comply with the relevant laws and regulations.

Public representatives/Members of the Public

R&I activity may affect the public directly (as research participants) or indirectly by the effects new developments have within society. Public representatives in EAUs represent the interests of non-experts in discussions. This representation may take the form of lay persons, patient or participant advocates, or members of civil society organisations and NGOs such as animal welfare or environmental protection groups. Lay persons may be considered as having expertise 'about the "community" of nonscientists in general'.[20] End-users, or representative of the end- user groups or organization, patient advocates represent the interests of those whose medical care is affected by the proposed research.

Skills and expertise of EAU members[21]

- The membership of an EAU should be arranged so that it encourages rigorous discussion and evaluation of R&I activity. This is best achieved by a membership that is *competent* (technically, ethically, and administratively), *independent* of the researchers and the institutions involved, *diverse* in backgrounds and expertise, and *representative* of the communities affected by its decisions.
- The EAU chairperson should possess strong administrative competence. This includes good interpersonal skills for managing group decisions and good communication skills to convey the EAU's decisions to researchers and supervisors.
- Those with expertise relevant to the activity under review should be included among the EAU's members. However, persons without directly relevant expertise should be an equally important section of the membership.
- EAU members should possess the following characteristics:
    - Relevant expertise (professional members) or an informed interest (non-professional members/lay persons, experts from other fields) in the R&I activity under assessment
    - Good communication skills, both written and interpersonal

[20] Solomon, Stephanie, "Too Many Rationales, Not Enough Reason: A Call to Examine the Goals of Including Lay Members on Institutional Review Boards", *Accountability in Research,* Vol. 23, No. 1, January 2016, pp. 4–22 [p. 15].

[21] *Philip Jansen, Wessel Reijers,David Douglas, Agata Gurzawska, Alexandra Kapeller & Philip Brey, Rok Benčin, Zuzanna Warso: SATORI Deliverable D4.1* A reasoned proposal for shared approaches to ethics assessment in the European context, December, 2016. p. 95.

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- An ability to evaluate the benefits, risks, and burdens associated with the specific research projects assessed
- An ability to engage in reasoned debate and discussion to reach and accept a balanced view of the research projects assessed
- Personal commitment to the goals of ethics assessment

Qualifications of EAU members

"One interviewee acknowledged that ethics professionals should be qualified, but added that experience, such as experience sitting on ethics committees, would be superior to formal training."[22]

[22] Rowena Rodrigues, Michael Madary, Andrea Porcari, Elvio Mantovani: SATORI Deliverable 7.2. Exploring the potential of conformity assessment techniques to support ethics assessment, February, 2017.

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Appendix 2.
RI/RE expert qualifications

Results from a qualitative expert interview study

ENERI, WP6, 6.1

2017

Tine Ravn, Robert Braun & Helmut Hönigmayer

The project leading to this application has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 710184.

1. Summary

The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. Work package 6 addresses the main objective in the project "to create an e-community/database (…) of European and whenever relevant international experts in the different fields of research ethics and integrity", which "should notably ensure the certification of the knowledge level of the experts" The main objectives are (1) to explore and develop indicators that are widely accepted in the heterogeneous field of RE/RI representing expertise in the two areas to be implemented in the expert data base; (2) to evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly; and (3) address the construction, mapping, and monitoring of central expert criteria.

Database design:

- Broad agreement among experts concerning the valuable aspect of establishing a database, adopting an inclusive, diverse and transparent approach to RE/RI expertise.
- For the next steps in the empirical programme, the expert interviewees raise a number of discussion points and themes valuable for further exploration:
    - The character of specific database objectives and key user needs
    - The structure and particular design of individual expert profiles (number of pre-defined and standardized categories, items, descriptions etc.)
    - Registration of experts (open access, management entry and monitoring, nomination procedure etc.)

Skills and qualifications:

- Most experts explicitly suggest adopting a broad, diverse and inclusive approach to RE/RI expertise, holding that such expertise can take many forms (expert types, RE/RI topics, organisational levels etc.) Formal and relevant education, as well as established experience within a certain RE/RI field of expertise, counts as the most important RE/RI expert criteria.
- Softer and emotional skills are highly prioritized. Expert interviews show that such skills need to feature into the individual database profiles and into the final sets of criteria/indicators in some form.

Access database training & certification:

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- An optional training course before database entering might be relevant, but a majority of interviewees would not make it mandatory. Several also question how to design a standardised course that would work as a common expert foundation.
- A few experts see a personal issued database certification as a good idea. Several view it as acceptable, but find it difficult to see its real value and the incentives for issuing one.
- The issue of training requirements and the issue of issuing a personal certification do not yet yield clear recommendations.
- The pros and cons of issuing a personal certification for database membership are not conclusive based on the interview study; the topic could be a prospect for further assessment.

Potential questions to be decided upon in the consensus conference series:

- Agreement
  - on the definition of database objectives and key user needs;
  - on structure and particular design of individual expert profiles;
  - on format of registration of experts;
  - on general approach to RE/RI expertise;
  - on formal and relevant education, RE/RI experience;
  - on optional training course;
  - on database certification;
  - on personal certification.

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2. Introduction

Research integrity (i.e. professional standards of conducting research) and research ethics (i.e. moral principles embedded in research) are pertinent topics in scientific research. Certainly, issues of research ethics (RE) and research integrity (RI) have always been inextricably linked with scientific processes. However, the changing and globalized nature of science in terms of techno-scientific innovations have given rise to new risks and ethical questions. Research infrastructures (i.e. funding and performance structures, journal and review systems, administration etc.) have been transformed and have - together with a rising number of cases of research misconduct (Anderson et al. 2013; Steneck 2006) - resulted in a greater need for the production and exchange of knowledge on how to practice, govern and fund sound and responsible research (IAP 2012; Ravn, Braun & Drivdal 2017).

The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. It is the ambition that such a shared platform - comprised of expert networks and groups, ethics and integrity commissions, assessment boards and expert databases etc. - may serve as a tool for promoting awareness and exchanging and disseminating knowledge, as well as substantiating and harmonizing cross-country experiences, standards, guidelines and 'best practices' within the fields of research ethics and research integrity.

Specifically, work package 6 (WP6) in ENERI addresses the main objective in the project "to create an e-community/database (…) of European and whenever relevant, international experts, in the different fields of research ethics and integrity", which "should notably ensure the certification of the knowledge level of the experts" (ENERI 2016, 40). Following this objective, it is stated that "an essential precondition for setting up and running this database is a meaningful as well as widely accepted definition of criteria that constitute expertise in the fields of research integrity and ethics" (ENERI 2016, 40). The main objectives in this regard are:

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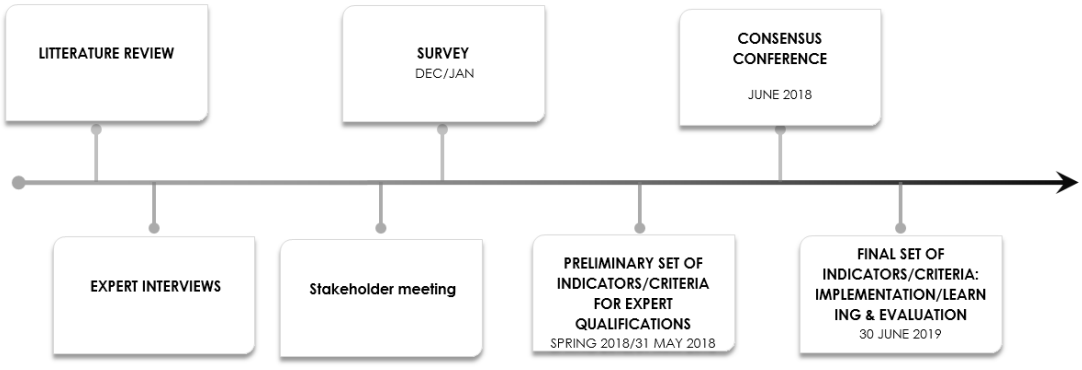
- To explore and develop indicators that are widely accepted in the heterogeneous field of RE/RI representing expertise in the two areas to be implemented in the expert data base
- To evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly

Hence, the key tasks are to certify experts and develop indicators to address the construction, mapping, and monitoring of central expert criteria. To explore how such criteria are to be defined and how RE/RI expertise is to be constituted, an initial literature review is conducted with the objective to review, map and assess existing literature, reports and European projects concerning potential expert qualifications/indicators (for the report see Ravn, Braun & Drivdal 2017). An empirical programme consisting of interviews with selected experts and an online survey that targets a variety of actors, stakeholders and organizations follows the literature review. As depicted in figure 1 below, the process of identifying, exploring and conducting expert indicators and criteria involves an initial stakeholder meeting and subsequent mid-term consensus conference, in order to discuss the preliminary set of RE/RI indictors and particular database objectives/design matters.

Figure 1. Overview of ENERI, WP6



The report at hand details the results from the expert interview study as well as key discussion points/results from the initial stakeholder conference. The expert interview study includes semi-structured interviews with 12 different research ethics and/or

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research integrity experts across Europe and across different institutional categories (see section below).

3. Methods and approach

The main reasons for opting for expert interviews as a first data collection source are to a) open up the heterogeneous fields of research ethics and research integrity, b) to inductively explore and generate knowledge on potential RE/RI expert criteria from a variety of key representatives and c) to collect contextual information that may complement insights and inform the remaining empirical programme.

In terms of generating new knowledge, the expert interview guide is constructed with a dual focus. The first part of the interview focuses on the particular interviewees' experiences and perceptions of key research integrity/ethics qualifications and skills in their own capacity as experts and from the vantage point of their own institution/organisation/network/committee. A question could for instance relate to which kind of existing skills and competences they regard to be the most important to e.g. their roles as REC members, or to their capacity as industrial or funding agency representatives etc. The second part of the interview addresses interviewees' perception of more general research integrity/ethics skills and qualifications concerning the expert database/e-community to be established by the project and EU commission. Interview focus areas in this regard is on database objectives, expert 'membership' criteria, RE/RI training possibilities and issues of certification (see interview guide, appendix A for details).

All expert interviews have been conducted in September and primo October 2017; 11 interviews were performed by phone or skype and the last interview was performed face-to-face. The interviews last between 30-60 minutes approximately. All interviewees were recruited via a personal email invitation (see appendix B) and interview appointments have subsequently been agreed upon through direct email correspondence.

The selection of experts/interviewees is based on an 'information oriented' (Bo 2005, 71) selection strategy, with the aim of reaching a broad group of RE/RI experts and to achieve variation according to the 'criteria of maximum variation' (Bo 2005, 72) and thus enhance in-depth understandings of potential expert criteria and qualifications. Variation has been

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pursued according to the following criteria: research ethics/research integrity focus; institutional category, geographical location, gender and age.

The institutional category endeavoured to include the following types of representation and experts positioned in:

- National research ethics committees (REC)
- Regional/local research committees (REC)
- European network of RECs (EUREC)
- National research integrity committees/offices (RIO)
- Local/university research integrity committees/offices (RIO)
- European network of research integrity offices (ENRIO)
- National funding organization (involved in ethics review)
- European funding organization (involved in ethics review)
- Government agency (ministry)
- Industrial advisor/consultant on ethics/CSR/corporate sustainability
- Research with expertise within the field of RE
- Research with expertise within the field of RIO

Hence, despite a relatively small interview sample, the sample strategy allows for a certain amount of variation and geographical and institutional distribution due to the experts' particular experiences/institutional affiliation and their meeting of relevant criteria of relevance for the objectives of the interview study. For the list of experts and their geographical, institutional and RE/RI expertise, see appendix C. The participating interviewees represent most of the pre-defined categories; however, a few interviewees represent more than one type of representation, and for this reason different emphasis is given to these expert roles in their interviews. Furthermore, interviewees have signed an informed consent template, see appendix D.

Interviews have been recorded and subsequently transcribed verbatim by student assistants. All interviews have then been coded thematically in the software programme Nvivo, which allows for a transparent and comparable management and analysis of the empirical data. Interviews have been coded according to a structured coding strategy in alignment with the set of focused codes derived from the key themes explored in the interviews. Notwithstanding, this coding strategy was combined with the process of initial

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coding (Charmaz 2006) that allows for an empirically grounded approach at where new themes/attention points are explored in an open manner.

The following sections will summarize and present the main results, discussions and attention points raised by the research ethics and – integrity experts. The first section explores the theme of database objectives, which exemplifies a substantial theme that primarily arose during the interviews as opposed to being a pre-defined interview subject.

3. Results from the expert interview study

3.1. Database objectives

The pre-defined objectives of the database are broadly characterized as constructing a database of international experts within the fields of research ethics and research integrity. A secondary aim of the database construction is to serve as a platform for creating an 'e-community' of experts in order to strengthen professional networks across relevant fields, disciplines and institutional representation as well as the interaction between relevant areas of RE and RI. In the expert interviews, several informants explicitly asked for specific database objectives, in order to provide the most effective and valuable database design recommendations. Similar calls for clearly defined objectives and user specifications were also raised in the stakeholder meeting (see section 4). While the process of constructing RI/RE qualification indicators and building a proper database design benefits from an open, generative and exploratory process, expert and stakeholder recommendations reveal a need to explicitly explore and identify particular user groups and their particular needs and wants for a database in the subsequent survey questions.

Based on the pre-defined database objectives, the potential value and use of an international expert database is clearly expressed; there is wide agreement that such a database might provide a useful platform to: "harmonize different national contact points" (Rouby, p. 16) and function as a common ground for knowledge exchange. The database is also viewed as a source of information where relevant experts and stakeholders can be identified when assembling review panels, misconduct committees or constructing local, regional, and national policy guidelines etc.

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Furthermore, it is evident from the interviews that experts recommend the database to be open and inclusive and that it be designed to allow for a transparent and diverse approach to expert qualifications and criteria, avoiding "the usual suspects" and "just consolidating the ivory tower of ethical expertise" (Dratwa, p. 11) as one expert points out. In this regard, several interviewees point to the valuable aspect of making it easier to keep track of relevant stakeholders and to "find the right people" (Hiney, p. 16) in terms of expanding one's search for relevant expertise beyond familiar networks and national/international known experts.

Two experts also explicitly give words to the changeable and contingent nature of the fields of RE/RI (and science more in general) and the ephemeral notion of what constitutes expertise within a given time frame and within different cultural, geographical and epistemic contexts etc. Both argue that the database should be approached as a "living organism" (Dubravka, p.10) and that the guiding principle of expertise behind it should originate from a multidisciplinary, inclusive and broad perspective that may "give room to other ways of showing expertise" (Rauhala, p. 16). In this regard, the latter expert also suggests making use of self-descriptions to allow expert members to describe their current and particular areas of expertise along with relevant experiences and preferred ways of working, for instance (p.9). This idea is also explicitly supported by a third expert, who suggests that the database features a "free-style box", in which to specify involvement in "local/national/international committees and working groups", for instance, in the individual expert profiles (Hiney, p. 9). Furthermore, the last-mentioned expert also provides a set of explicit recommendations on how to structure and stratify the database. One can easily end up with a great number of main- and sub classifications as she points out, and she suggests to only include "fairly broad classifications" which stratify in terms of *type* (for instance practitioners, policy experts, academic experts), particular sets of *experience* and by specific *topics* (for instance publication ethics, types of misconduct, data management and development of teaching curricula) (Hiney, p. 6-8).

The issue of how to design the database is closely interlinked with the question of what constitutes RE/RI expertise and qualifications; while as an independent subject specific design issues such as registration, number of categories/items/descriptions and so forth are more sporadically taken up in the interviews. Therefore, such design issues are in and of themselves a very relevant subject for further survey exploration. As mentioned above, some experts recommend a semi-structured profile design, whereas one expert prefers a "deeply structured" strategy to avoid a "phonebook" set-up (Claesen, p. 5). Another issue for further assessment concerns how expert members are to register into the database. One expert explicitly recommends a nomination strategy where "we collect [expert] suggestions

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from competent national bodies, which we have faith in" (Madsen, p. 12). Hence, the question of database openness – a feature that many experts underscore – remains to be further explored in terms of access and registration.

3.1.1. Recapturing points

- Broad agreement among experts concerning the valuable aspect of establishing a database, which adopt an inclusive, diverse and transparent approach to RE/RI expertise.
- For the next steps in the empirical programme, the expert interviewees raise a number of discussion points and themes valuable for further exploration:
    - The character of specific database objectives and key user needs
    - The structure and particular design of individual expert profiles (number of pre-defined and standardized categories, items, descriptions etc.)
    - Registration of experts (open access, management entry and monitoring, nomination procedure etc.)

3.2. RI/RE skills and qualifications

The expert interviews speak both to the issue of particular RI/RE skills and qualifications from the part of the individual experts and his/her institution, as well as the experts' views on relevant sets of database expertise. Despite variation, the statements, discussions, and recommendations that emerge from the interviews centre on the core questions of what constitutes an 'expert': are expert criteria defined by specific types of education, years of practical experience, teaching experience or analytical, administrative or interpersonal skills, for instance? Who is to define expertise? Furthermore, to which degree is it possible – and not least suitable and desirable – to standardise RE/RI expert qualifications?

As a general impression, interviewees seem to share a general consensus as to the rather nebulous and indefinable notion of what RE/RI expertise is, with interviewees agreeing on a series of key points. There are many types of experts (such as practitioners, policy/law experts, academic experts etc.). Expertise can be possessed within a large number of RE/RI topics (such as publication ethics, codes of conduct, ethics review, data management, FFP, QRPs, teaching curriculum development, bibliometric etc.) and expertise may relate to one or several organizational levels (e.g. local, regional, national, European or international areas of knowledge). Moreover, while expert interviewees provide explicit examples of core competences and skills in regard to their own position and to the database, it is also evident that no fixed expertise definition exists and that RE/RI qualifications, in many ways, can be

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regarded as intrinsic to research processes and may occur as a kind of tacit knowledge (Polanyi, 1958). This seems to be particularly the case for the field of research integrity which – compared to the field of research ethics – appear less established in terms of the production of in- and cross-country legislation and in regard to instituted procedures, guidelines and university courses specifying professional standards of conducting research (see also Ravn, Braun & Drivdal 2017).

Furthermore, the academic breath, complexity and multidisciplinarity of both fields add to the challenge of stipulating clear expertise standards for RE/RI skills and competences. In this regard, most experts explicitly suggest adopting a broad, diverse and inclusive approach to RE/RI expertise, highlighting the benefits of collective skills on the one hand, and highly specialised areas of expertise on the other. Then, from a broad perspective, interviewees emphasise formal education and relevant experience as the most important competences. Training in ethics/integrity issues are relevant, but several experts point out that the completion of a formal course in research ethics or integrity do not make one an expert in such areas. They highlight seniority (or similar well established) experience within a given area of expertise as the most important competence, in combination with a relevant formal education. In addition to such competences, interviewees underline an array of core skills relevant for their type of RE/RI involvement/representation. These are shown in table 3.2.1. below, along with organisational levels of expertise, skills that could be further pursued and potential frictions between currently employed qualifications.

3.2.1. Interviewees' institution – competences and skills

Table 3.2.1. Core competences and skills related to different types of RE/RI representation

Type of RI/RI involvement	**Type of representation** (legal experts, chair, RI officer etc.)	**Type of experience/competences** (educational, administrative, network etc.)	**Skills required** (hard, soft, process, emotional skills)	**Organisational level of expertise** (institutional, national, regional, international)	**Further pursuing of skills**	**Frictions among skills**	**Source(s)**
Ethics expert in H2020	Ethical appraisal/review	Formal education – competences in ethics "guidelines, rulebooks, recommendations" (p.2) Research experience	Communication-al skills Interpersonal Open-mindedness Critical thinking Independence Analytical skills Eye for details	European			Vejnovic, p. 2-4
University RIO	Head of committee	Deep knowledge of RE/RI issues Senior scientific experience	Scientific skills/integrity Committee members:	institutional		Discipline differences	Madsen, p. 1, 7

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			Process skills Named persons: interpersonal skills				
European Association of research managers and administrators	Managing director	Knowledge of ethics + national/international guidelines,	Communication-al skills Research skills	European			Claesen p. 1-2
National funding org.	Head of unit	Formal education Ethical competences		National			Hiney p. 9
European funding org.	Head of European Group on Ethics in Science and New Technologies	Member composition: discipline and expertise diversity Gender, geographical prominence, age, institutional background	Thinking "outside the institutional buzz" (p.3) interpersonal and emotional skills Process skills Deliberation Open-mindedness "skills of peace-making, conflict-resolution, negotiations" (p. 6) Turning ideas into recommendation	European			Dratwa p. 3-4
Perma-nent Working Party of Research Ethics Committees	Co-founder	As a researcher fulfill: "scientific quality, conformity with law and ethical acceptability" (Doppelfeldt p. 1)	Researcher: commitment to publication (p.2) Societal/health care awareness/ impact Ethic commitment Ethical thinking	National		Contra-dictions in terms of normative ethics	Doppel-feldt p.3-5
National REC	Director	Ethical and legal expertise Professional qualifications	For committee members: Ethic skills Interpersonal (communicational, deliberation) Open-mindedness Societal awareness	National		Discipline differences	Ingierd p. 4, 5, 7
Journal editor	Admini-strative	Policy guidelines Codes of conduct		International			Marusic, p. 3,
Academic expertise	Researcher	Education and practice (both at an individual and institutional level)		National International	Clearer/detailed institutional	Pressure to publish	Marusic, p. 5-6

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in RE and RI	Ethics advisor	Research ethics competences Scientific awareness/understanding	Personal commitment Communication-al skills		guidelines /frameworks		Rauhala p. 3, 5, 6
Industrial advisor		Scientific education (master level minimum)	Collaboration skills "listen to different perspectives and taking into account the needs of different domains" (p.6) Decision-making skills	National international	Promote openness and transparency + towards negative results	Drive to get positive results and also trustworthy results Pressure to publish (medical/collective success and not just individual)	Gilis, p. 6, 9-10
National funding org.	Legal	Guidelines of soft law Insights into International practices and guidelines Ethics assessment/ review competences/knowledge of good scientific practices Transparent, impersonal, confidential treatment of funding proposals Seniority experience	"understand the needs of other stakeholders", p.4 Cultural awareness	National European		Cross-country variation in RI definitions	Rouby, p. 4, 7

As shown in the table above, different types of experts highlight different types of experience and competences in accordance with their field of expertise and RE/RI representation. Hence, ethics assessment/review competences are emphasized for ethics research projects reviewers, while knowledge of integrity guidelines and codes of conduct are mentioned as important competences for journal editors, for instance. Despite variation, similarities as to core competences and skills appear somewhat consistent across different areas of expertise. Regarding competences, the following types of acquired knowledge are suggested:

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- Ethical competences (deep knowledge of national and international regulation, policy and guidelines)
- Integrity competences (deep knowledge of national and international regulation, policy and guidelines)
- Research/science competences (research experience)
- Legal competences
- Ethics assessment/review competences
- Integrity assessment/review competences

Experts agree on the importance of a number of skills related to communication, deliberation, collaboration and management, among others. Below, these are summarized and grouped according to hard skills (e.g. education, technical), soft skills (e.g. communicative), process skills (e.g. administrative/management) and emotional skills (commitment, open mindedness).

Hard skills:

- Analytical skills
- Scientific skills
- Ethical commitment/thinking/abilities
- Critical thinking
- Assessment/ review

Soft skills:

- Communicational
- Interpersonal
- Eye for details
- Deliberation
- Peace-making, conflict-resolution
- Collaboration

Process skills:

- Administrative/management
- Turning ideas into recommendations/practice
- Decision-making

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Emotional skills:

- Open-mindedness
- Independence
- Societal/cultural/health care awareness/impact
- Personal commitment

Regardless of RE/RI expertise type, experts emphasize and prioritize a host of emotional skills as essential for working with and within areas related to research ethics and integrity. Being open-minded towards other perspectives, as well as able to collaborate, for instance, is seen to minimize potential frictions between different discipline practices/guidelines etc. and more broadly between different (normative) perceptions of ethical/integrity standards across research fields, institutions and countries, among others.

3.2.2. Database expert competences and skills

The interviewees' recommendations for relevant database expert competences and skills are very similar to those mentioned in terms of their own/institutional/organizational sets of expert criteria. A broad, multidisciplinary and inclusive approach to RI/RE expertise are once more highlighted as well as the general competences of relevant formal education and recognized/profound RI/RE experience are perceived to be the most important competences. Soft and emotional skills, such as open mindedness and the ability to discuss in a multidisciplinary fashion are also mentioned as criteria for the inclusion of a database expert. Furthermore, one expert also points to the importance of ensuring that database members do not have any conflict of interest in roles as experts (Rouby, p. 10).

Different types of experts are mentioned as potential candidates for the database: experts with an "omnibus" function; local and national RIO's, researchers in RE/RI; medical researchers; REC members; editors; publishers; individuals with national/EU project evaluation/review experience; RE/RI university teachers; research funders; RE/RI communication trained individuals; specialists in constitutional law/applied ethics/philosophy/social science/psychology/economy/criminology; practitioner network members (e.g. ENRIO); RE/RI policy experts. A few interviewees furthermore mention that lay people might be relevant to include in the database similar to the composition of REC's.

3.2.3. Summary of main points

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- Most experts explicitly suggest adopting a broad, diverse and inclusive approach to RE/RI expertise, holding that such expertise can take many forms (expert types, RE/RI topics, organisational levels etc.)
- Formal and relevant education, as well as established experience within a certain RE/RI field of expertise, counts as the most important RE/RI expert criteria.
- Softer and emotional skills are highly prioritized, too. While these "are very difficult to quantify" (Rauhala, p. 15), the expert interviews show that such skills need to feature into the individual database profiles and into the final sets of criteria/indicators in some form.

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3.3. Database training and certification

3.3.1. Access training course

Interviewees are asked to assess whether they would recommend potential database experts to undergo an initial research ethics/integrity training programme in order to become members. While a majority of interviewees find initial – but optional – training relevant, several interviewees express scepticism about the design of a "standard course" and its ability to provide relevant introductory content for all kinds of experts, arguing that such a course "is not a guarantee that you get people that know their job" (Rauhala, p. 13) since expertise is primarily "experience-based" (Rauhala p. 14). Another expert points to the issue of "who should have the authority to sort of say that 'this is what you should do and what you should know'" (Claesen p. 6). The latter expert does however recommend some kind of initial and objective quality assurance/testing mechanism to verify member expertise (p. 6-7).

Two interviewees explicitly recommend an introductory training course to be mandatory to make sure experts are "at the same kind of starting level" (Marusic, p. 10) and because:

> "… our countries are different, we have a different ways of dealing with things, and then it is good to have that, we were talking about this standardized training. So in that way all experts in the database will be communicating the same language or the same level, at least at the start" (Vejnovic, p. 7).

Both of the above-mentioned experts, along with one additional expert, are also in favour of a personal training certificate to be issued after course completion. The majority of interviewees are not in favour of a mandatory course, primarily because potential member experts are already perceived to be expert representatives of their respective fields (Gilis, p. 13) and because it would discourage qualified and busy experts from becoming members (Doppelfeldt, p. 10; Madsen, p. 11).

3.3.2. Certification

In the expert interviews it is discussed whether a form of personal certification should be issued to members of the database as a validation of RE/RI skills and competences. Expert opinions, however, are divided. Only a few interviewees explicitly express a particularly positive view of personal certification, with one arguing that it might be a credential to use internationally and outside of one's research institution. Several experts state that a personal certification would be acceptable, but find it rather difficult to see the clear benefits and incentives. Such difficulties also relate to the issue of expertise standardisation and to the objectives of the database. One expert suggests that it could "increase visibility of the [European integrity] network in the database to give a special voucher or special part, a

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special additional line that can be put on to the CV" but that it at the same time "would be sort of a proxy for the fact that they followed a certification" (Dratwa, p. 10). Nonetheless, the pros and cons of issuing a personal certification for database membership are not conclusive, based on the interview study, and the topic could probably be a prospect for further assessment.

3.3.3. Summary of main points

- An optional training course before database entering might be relevant, but a majority of interviewees would not make it mandatory. Several also question how to design a standardised course that would work as a common expert foundation.
- A few experts see a personal issued database certification as a good idea. Several view it as acceptable, but find it difficult to see its real value and the incentives for issuing one.
- The issue of training requirements and the issue of issuing a personal certification do not yield clear recommendations. Both issues would be highly relevant to pursue in the subsequent empirical programme (survey and consensus conference).

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4. Results from the ENERI stakeholder conference

The stakeholder conference took place in Athens, September 2017 and brought together 55 different stakeholders from universities, industry, science journalism, ministries as well as project participants from several European projects on research ethics and research integrity. The conference aimed to bring together expertise from various fields and perspectives to discuss central questions as to the current and future state of RE/RI in terms of practices, infrastructures, committee compositions, among other related subjects. The conference also included the WP6 workshop on "what constitutes expertise and qualifications in RE/RI?"[23]

The objective of the workshop was to receive stakeholder input on what constitutes expert skills, competences and qualifications within the fields of research ethics and research integrity. These stakeholder input were then to enter into the WP6 empirical programme that aims to explore and establish a set of relevant expert criteria/indicators for the creation of a European e-community/database of international experts (see introduction).

The workshop was designed in a participatory manner utilizing the World Café format (Slocum, 2003). Stakeholders were divided into four groups with each group discussing a set of five questions related to the following themes: a) skills and competences b) qualifications c) certification d) EU database of RI/RE experts (see questions in table 4.1 below). All groups were to reach consensus on all questions and report their answers in a table format using flip charts. One group representative subsequently presented group findings in the joint plenary session.

In terms of results, all groups were highly engaged in effective and wide-ranging discussions on the subjects pre-determined for debate. While not all groups reached consensus on the best ways to proceed with constructing the database/establishing expert criteria, consensus was reached on what type of key discussions need to be settled in the further phases.

The group discussing the **EU database on RI/RE expert** emphasized the following key points/discussions:

[23] This summary also features into a modified summary report from the Athens meeting.

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- It is decisive to establish the main objective, with building a database of experts in order to tailor the most appropriate and effective database design – for instance who are the main target groups/end users? It was also suggested to pilot the database in a closed environment to assist with designing the (search) tools. It was also recommended to designate the database as a 'registry' instead of a database. The group also raised the important question of how to monitor/register experts and the need to be highly aware of the different implications of different exclusive/inclusive criteria.

- In general, there seems to be consensus that the database should be open and inclusive and adopt a diverse approach to expert criteria that mirrors the complexity of RE/RI "in and around research".

In terms of key **expert skills and qualifications**, the two groups discussing the matter gave emphasis to the following set of skills/competences/qualifications as important to possess:

- Scientific literacy; awareness/understanding/interest in ethical principles/issues; diversity in backgrounds; assessment skills (benefits, risks, societal challenges); mediation/deliberation/decision-making skills; awareness of societal/cultural differences → education, experience, interpersonal skills

The group that discussed the pros and cons of **certification** reached agreement on a positive approach towards certification but they put forward that it should be a personal issued certification related to portfolio/CV.

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Skills and competences:

- From a collective standpoint (Ethics Units [EUs]) what skills and competences must/should an Ethics Unit have?
- Please prioritize such skills and competences (eg. must have-s/nice to have-s)
- Which competencies and skills do you regard to be the most important in RE/RI assessments on an individual level for any member of the Ethics Units?
- Please group these as hard skills, soft skills, process skills and emotional skills; which do you find especially important?
- Are there any skills all members of Ethics Units should possess while are there skills that only specific members must have?

Qualifications:

- What kind of formal or informal qualifications must Ethics Unit members possess? (Ethics training; experience in ethics assessment; legal; philosophical; gender; sociology; etc.)
- Are some of these qualifications more useful than others? (education, experience, emotional skills etc.)
- Please prioritize skills and qualifications?
- Are there any qualifications that can be quantified/specified? (eg.: 3 years of research experience; 3 ethics assessment projects; formal training/education)
- Is there a need for such quantification? Please explain

Certification:

- Should there be certification applied in assessing qualifications?
- On which level should these qualifications be applied: process; training offered or personal?
- Are there any frictions/contradictions between currently employed qualifications?
- How are these contradictions addressed? How may they be solved?
- Should there be a central body (EU level) offering such certifications or should any such there be an accreditation process for certificates/certificators?

EU database of RI/RE experts:

- In order to build an European database of international experts within the field of research ethics and integrity, which types of criteria and qualifications do you think experts need to poses to become a member of the database? (education, experience, teaching, process and emotional skills?)
- What are "must have" criteria and qualifications?
- Which criteria and qualifications would be "nice to have"?
- Would European institutions – including yours – benefit from more standardised practises, processes and qualifications?
- Should there be any particular research ethics and integrity training programs or upgrading of skills required? (Initial training? Recurring upgrading?)

Table 4.1. Workshop questions addressed in the Athens stakeholder meeting

4.1.1. Summary of main points– expert study and stakeholder recommendations

The expert study as well as the stakeholder conference point to several key recommendations, discussions and awareness points, which would be beneficial to explore further in the following empirical program and hence in terms of constructing a preliminary set of RE/RI criteria/indicators:

- Data base objectives should be further explored and determined in terms of user needs.
- The issue of database design that occupied the stakeholder workshop compared to the expert interviews, but database access, structure, key features, profile set-up and pre-defined classifications etc. are all topics, which will require further consideration.
- Interview experts and stakeholders highlight many of the same core RE/RI competences and skills but agree to adopt an inclusive, broad and multidisciplinary approach towards RE/RI expertise.
- Stakeholders reached consensus on the issue of certification and agreed to the advantages of issuing a personal certification for expert database membership. Expert interviewees, in turn, were much more divided in their view on the benefits of certification.

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6. Further information

An Interview guide - qualitative study of RI/RE expert qualifications

A. Introduction

- Short presentation/recap of interview objectives
- Information about lack of anonymity
- Informed consent
- Information about recording/handling of interview material

B. Background & organisation (2 mins)

1. Could you please tell me in a few sentences how your work is related to research ethics and integrity?

2. Could you also tell me how your institution/organisation/committee/network work with RE/RI? What are your main responsibilities? (e.g. advisory role, decision-making power, legal mandate, review, project coordination, teaching etc.)

C. RE/RI skills/expertise/qualifications (25 mins)

Our main focus in this interview is on RE/RI expertise, qualifications and certification.

Therefore:

3. Which existing skills and competences do you regard to be the most important in your institution/organisation/committee/network? – Individual qualifications/collective-team competences? (Will you describe these qualifications in detail?)

4. What kind of formal or informal skills and qualifications must members/employees/researchers possess? (Ethics training; experience in ethics assessment; legal; philosophical; gender; sociology; etc.)

5. You have mentioned different types of skills. Could you group these as hard skills (e.g. education), soft skills (e.g. communicative), process skills (e.g. adm./management) and emotional skills (commitment, open minded) that you find especially important?

6. Are some of these skills and qualifications more useful than others? (education, experience, emotional skills etc.) Could you prioritize them?

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7. Are there any qualifications that can be quantified/specified? (e.g. 3 years of research experience; 3 ethics assessment projects; formal training/education). Is there a need for such quantification?

8. Are there any frictions/contradictions between currently employed qualifications? If yes: How are these contradictions addressed? Solved?

9. Which competences/qualifications – if any - should be further pursued? And how?

General EU database qualifications:

10. In order to build a European database of international experts within the field of research ethics and integrity, which types of skills and qualifications do you think experts need to poses to become a member of the database? (education, experience, teaching, process and emotional skills?) – within specific scientific disciplines?

11. What do you think are "must have" criteria and qualifications? Why?

12. In addition to those, which criteria and qualifications would be "nice to have"? Why?

13. In your opinion, do you think European institutions – including yours – would benefit from more standardised practises, processes and qualifications - and hence greater harmonisation among countries? Why? (pros and cons?)

D. Training/certification (10 mins)

In interviewees' institution:

14. Is there any particular RE/RI training programs or upgrading of skills required in your institution/organisation/committee/network?

- if yes: Initial training? Recurring upgrading? Which type of training programme is applied?

- if no: do you think members/employees would benefit from ethics/integrity training? Which type? Why?

15. Should there be also certification applied? On which level: process; training offered or personal?

EU database:

16. Do you believe it should be mandatory to undergo an ethics/integrity training programme to become a member of the European expert database? If yes: do you think completing the expert training programme should result in a personal training certificate?

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17. In your opinion, do you think a form of issued personal certification should be required to be a member of the European expert database? (pros and cons?)

E. Other (5 mins)

18. Before we finish – is their anything else you think we need to cover?

B. Email invitation to expert interviewees

Dear,

As part of the EU funded project ENERI (European Network of Research Ethics and Research Integrity http://eneri.eu/), the European Commission wishes to build an e-community and database of international experts within the field of research ethics and integrity. Through an empirical research programme, ENERI aims to explore and establish a set of relevant expert criteria/indicators that cover a broad set of key expert skills and qualifications within these fields.

In your capacity as a renowned expert within the field of research ethics and integrity, we take the liberty to contact you to ask whether you will be able to participate in a short expert interview within the next two weeks?

The interview will take place by phone or skype and last between 30-50 minutes. The interview will focus on your perception of key RI/RE skills and qualifications in terms of your own work within these areas and in regard to the European expert database.

Would you be able to participate? Possibly, you can email me with a preferable time to reach you by phone to set up the interview appointment.

Kind regards,

Tine Ravn, PhD, Assistant Professor

On behalf of

The Institute for Advanced Studies, Vienna; the Danish Centre for Studies in Research and Research Policy, Aarhus University and the ENERI consortium

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INSTITUT FÜR HÖHERE STUDIEN
INSTITUTE FOR ADVANCED STUDIES
Vienna

THE DANISH CENTRE FOR STUDIES IN RESEARCH AND RESEARCH POLICY
DEPARTMENT OF POLITICAL SCIENCE
AARHUS UNIVERSITY

eneri

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C List of informants

	Inst. Category/ type of RI/RI involvement	Name	Institution/organisation/network
1.	National REC	Helene Ingierd, Director	The National Committee for Research Ethics in Science and Technology (NENT), Norway
2.	Ethics expert in H2020 Expert associate in the center promotion of science Researcher	Dr. Dubravka Vejnovic	Expert associate in the Center for the Promotion of Science, Belgrade, Serbia Researcher at the institute of human genetics, Faculty of Medicine, University of Belgrade
3.	European network of RECs Permanent Working Party of Research Ethics Committees	Prof. Dr. med. Elmar Doppelfeld	Chair of EUREC Founder of Permanent Working Party of Research Ethics Committees in Germany
4.	Researcher, manager	Prof. Mgr. Ing. Petr Kratochvíl, Ph.D.	Director of the institute of international relations in Prague, Czech Republic
5.	University RIO	Palle Bo Madsen,	Head of The Committee for Responsible Conduct of Research Aarhus University, Denmark
6.	European networks of RIOs National funding organisation	Asael Rouby	Vice-Chair, ENRIO Programme Manager, Legal Adviser, Research Integrity Office, The Luxembourg National Research Fund (FNR)
7.	National funding org.	Maura Hiney	Health Research Board (HRB) Head of Policy, Evaluation and External Relations, Dublin, Ireland

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8.	European advisory body of the President of the European Commission	Jim Dratwa	Head of European Group on Ethics in Science and New Technologies
9.	European Association of research managers and administrators (EARMA)	Nik Claesen	Managing director, Belgium
10.	Industrial representative	Anja Gilis	Janssen, Pharmaceutical Companies of Johnson and Johnson, Belgium
11.	RE researcher Research ethics coordinator	Dr. Marjo Rauhala	Unit of Gender Competence Office,Technical University, Vienna, Austria
12.	Journal editor RI researcher	Dr. Ana Marusic	Professor of Anatomy and Chair of the Department of Research in Biomedicine and Health at the University of Split School of Medicine, Split, Croatia Co-editor in Chief of the *Journal of Global Health* and President of the European Association of Science Editors

D. Informed consent template

European Commission Horizon 2020 Framework Project (H2020), **Project ID**: 710184 - European Network of Research Ethics and Research Integrity (ENERI)

Informed Consent for participation in ENERI Expert Interviews

Project and expert interview objectives

The "European Network of Research Ethics and Research Integrity" (ENERI) broadly wishes to establish an operable platform of actors in the fields of research ethics and research integrity. As part of the project, the European Commission wishes to build an e-community and database of international experts within the field of research ethics and integrity.

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Through an empirical research programme, among here a set of expert interviews, ENERI aims to explore and establish a set of relevant expert criteria/indicators that cover a broad set of key RI/RE expert skills and qualifications.

Audiovisual material

Each expert interview will be recorded on an audio device for the purpose of analysis. It will be stored in a safe place at the investigators facilities. Each participant may demand removal of his/her recordings by simple request.

Anonymity

Interviewees participate in their position as experts within their field and will not appear anonymous. However, complete interview transcript will only be accessible to members of the project team and handled with confidentiality.

Delete as necessary

1. Have you been informed about the objective of the interviews? YES/NO
2. Have you had an opportunity to ask questions and discuss this study? YES/NO
3. Do you understand that you are free to withdraw from this study YES/NO
   - at any time? Without giving any reason for withdrawing?
4. Do you agree to take part in this study YES/NO
5. Do you accept the way in which we use your data in line with established data protection guidelines and regulations? YES/NO
6. Do you accept that you participate as an expert and that full anonymity is not possible to grant? YES/NO

Participant's signature: Contact's signature:

Name in Block letters:

Day/month/year

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Appendix 3.
RI/RE expert qualifications

Results from a quantitative survey

ENERI, WP6, 6.1

2018

Robert Braun, Magdalena Wicher & Tamara Brandsätter

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1. Summary

The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. Work package 6 addresses the main objective in the project "to create an e-community/database (…) of European and whenever relevant international experts in the different fields of research ethics and integrity", which "should notably ensure the certification of the knowledge level of the experts" The main objectives are (1) to explore and develop indicators that are widely accepted in the heterogeneous field of RE/RI representing expertise in the two areas to be implemented in the expert data base; (2) to evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly; and (3) address the construction, mapping, and monitoring of central expert criteria.

We have created an empirical program to address the above mentioned issues in a systematic way. The first step of the program was an extensive literature review and desktop research, followed by a quantitative research interviewing experts. The next phase of the program is the qualitative survey. This will be followed by a series of consensus conferences to involve potential users of the database as well as lay persons and validate our findings.

Key takeaways from the quantitative survey:

Skills and competences: Based on the survey we may conclude that respondents value 'experience' or praxis in RE/RI assessment the most; while also prioritizing that experts possess some theoretical ethics/philosophy (and to a lesser extent 'legal') knowledge to back up their practical experiences. When assessing required skills, respondents say that experts should be personally committed open-minded and impartial people, with analytical minds to solve the ethical/moral dilemmas that may arise as problems, while also being able to convey and deliberate their potentially diverging opinions or point of views.

Use of database: Respondents find an international database/e-community to be a very useful initiative and name various uses from the potential use to 'find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. and 'find research ethics experts for European/international networks'.

Database design: Respondents suggest that the design of the database should (pre)define all skills and expertise of the database members as well as years of practical experience and believe these should be somewhat more important than specific educational background. When it comes to specific skills and competences respondents value RE/RI experience as well as previous experience in RE/RI commissions experience the most, closely followed by

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scientific/research experience. As for the structure of the database, respondents value a selection of short self-descriptions based on key areas of expertise, rather than tick-off standardized categories or a few standardized themes and blank cells to be filled in with whatever the expert finds important.

Training: The majority of respondents claim that training should only offered on a voluntary basis and not be made mandatory and 'any ethics/integrity training' should be accepted as opposed to a certified training by an official body.

Certification: When defining the type of certification required for the training a majority would opt for a certification to be received at the end of the completion of the course as opposed to the requirement of certifying the teaching method of the training.

Proposed questions for the consensus conference series:

- Should a broad, diverse and inclusive or a normative, limited approach to RE/RI expertise be applied? (expert types, RE/RI topics, organisational levels etc.)
- Individual profiles should be highly structured and include a large number of 'tick-off' standardised categories or should be semi-structured and only include only a few predefined key areas/themes of expertise + open categories?
- Should the database offer self-registration or members should be managed and monitored by a relevant EU management team and/or be nominated by relevant national governmental and institutional bodies?
- Should members go through a training course before being allowed to register in the database?
- Should individual profiles indicate years of experience within particular areas of expertise or experience need not be quantified?
- Should the database require personal certification of any type or such certification is not required?

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2. Introduction

As discussed in our "RI/RE expert qualifications/Results from a qualitative expert interview study (Ravn et al. 2017) research integrity (i.e. professional standards of conducting research) and research ethics (i.e. moral principles embedded in research) are pertinent topics in scientific research. The European ENERI project (European Network of Research Ethics and Research Integrity) aims to build a shared platform for advancing knowledge, capacities and practices concerning research ethics and research integrity. It is the ambition that such a shared platform - comprised of expert networks and groups, ethics and integrity commissions, assessment boards and expert databases etc. - may serve as a tool for promoting awareness and exchanging and disseminating knowledge, as well as substantiating and harmonizing cross-country experiences, standards, guidelines and 'best practices' within the fields of research ethics and research integrity.

Specifically, work package 6 (WP6) in ENERI addresses the main objective in the project "to create an e-community/database (…) of European and whenever relevant international experts in the different fields of research ethics and integrity", which "should notably ensure the certification of the knowledge level of the experts" (ENERI 2016, 40). Following this objective, it is stated that "an essential precondition for setting up and running this database is a meaningful as well as widely accepted definition of criteria that constitute expertise in the fields of research integrity and ethics" (ENERI 2016, 40). The main objectives in this regard are:

- To explore and develop indicators that are widely accepted in the heterogeneous field of RE/RI representing expertise in the two areas to be implemented in the expert data base
- To evaluate the experiences gained with the validity and usability of the indicators and to adapt them accordingly

Hence, the key tasks of certification of experts and the development of indicators address the construction, mapping, and monitoring of central expert criteria. To explore how such criteria are to be defined and how RE/RI expertise is to be constituted, an initial literature review is conducted with the objective to review, map and assess existing literature, reports and European projects concerning potential expert qualifications/indicators (for the report see Ravn, Braun & Drivdal 2017). As a second step an empirical programme consisting of interviews with selected experts follows the literature review. This is followed by an online survey that targets a variety of actors, stakeholders and organizations. As depicted in figure 1 below, the process of identifying, exploring and conducting expert indicators and criteria involves an initial stakeholder meeting and ends with a series of consensus conferences, in

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order to discuss the preliminary set of RE/RI indictors and particular database objectives/design matters.

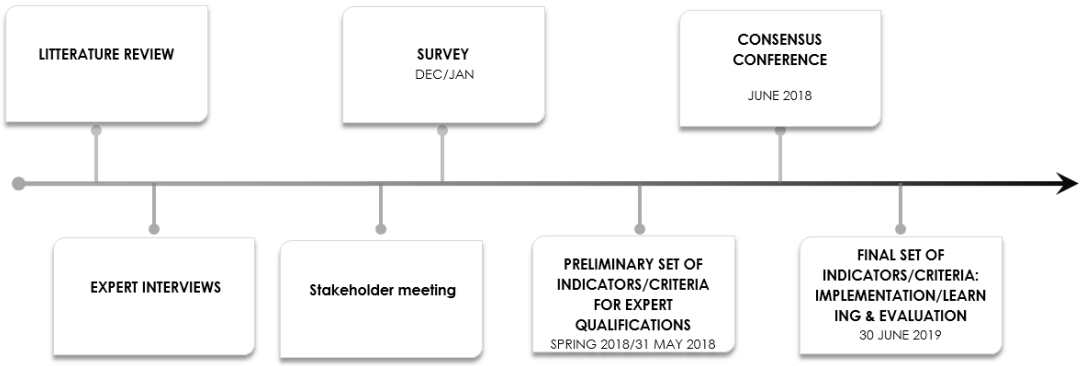

Figure 1. Overview of ENERI, WP6

The report at hand details the results from online survey that targets a variety of actors, stakeholders and organizations.

3. Methods and approach

The main reasons for opting for an online survey as an addition to the expert interviews are to a) open up the heterogeneous fields of research ethics and research integrity to a variety of actors, b) to inductively explore and generate knowledge on potential RE/RI expert criteria from a variety of key representatives and c) to collect structured information that may complement insights and inform the remaining empirical programme, especially assist in fine tuning the questions to be discussed at the consensus conference series.

The questionnaire starts with a description of the ENERI project with a focus on the e-community/database of European and international experts in the different fields of research ethics and integrity. The questionairre also describes the rationale of the database as assisting responsible people to set up oversight bodies, committees, teaching and training and other processes involving people with the appropriate skills, competences and experience.

The questionairre was created in January 2018 and was distributed by the European Network of Research Integrity Offices (ENRIO) network as well as was shared at the EUREC members meeting that took place on 15th of February 2018 in Berlin. The target sample was

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100 respondents; after intensive communication and repeated reminders all together 125 respondents have filled in the questionnaire. An online questionnaire tool was used to collect answers; answers were anonymized through the tool.

In selecting respondents we used non-probability sampling as randomization was not possible in order to obtain a representative sample. Following up on the expert interviews and utilizing the core expert networks of RE/RI, ENRIO and EUREC, we used expert sampling as a subset of non-probability sampling.

We contacted and utilized the membership of two main RE/RI organizations with a broad expert base and good geographic distribution:

- European network of RECs (EUREC)
- European network of research integrity offices (ENRIO)

Utilizing these networks even the non-probability sampling strategy allows for a certain amount of variation and geographic and institutional distribution due to the experts' particular experiences and institutional affiliation.

The following sections will summarize and present the main results of the online questionnaire.

4. Results from the questionnaire

4.1. Competences and skills

The first set of questions aimed at getting an overview of which competences (knowledge) and skills (practical abilities) should experts in the database possess.

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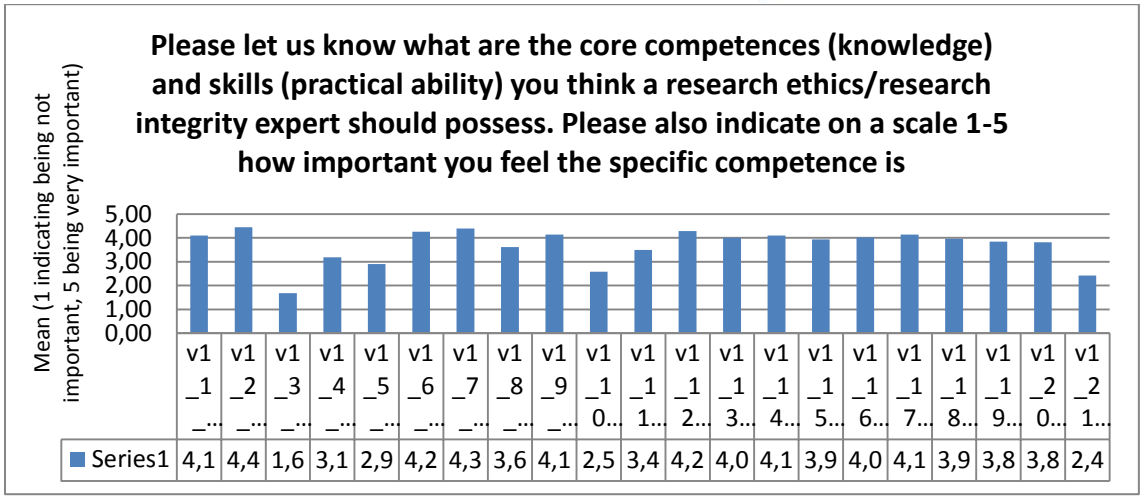

Respondents found "research/science" competence the most important (4,45) closely followed by 'ethics assessment' (4,27) and 'integrity assessment' (4,39) competencies. This confirms our findings in both the literature review and the expert interviews that experts value experience in assessment as the most important competence in being an 'expert' in RE/RI. Aside from experience respondents value 'ethics/philosophy competences' (4,10) high while 'legal competences' (3,18) relatively lower. Respondents seem to value 'religious competences' (1,69) as the least important in RE/RI expertise.

When assessing required skills of RE/RI expertise 'impartiality' (4,29), and 'open mindedness' (4,14) are rated as the most important skills, while 'personal commitment' (4,14) is also valued. 'Administrative' (2,57) and 'technical' (2,43) skills are valued the least, while 'analytical' (4,10), 'problem solving' (4,00) and 'debate/deliberation' (4,02) skills are also highly valued.

Key points:

Based on the survey we may conclude that respondents value 'experience' or praxis in RE/RI assessment the most; while would like to see experts possess some theoretical ethics/philosophy (and to a lesser extent 'legal') knowledge to back up their practical experiences. When assessing required skills respondents say that experts should be personally committed, open-minded and impartial people, with analytical minds to solve the ethical/moral dilemmas that may arise as problems, while also being able to convey and deliberate their potentially diverging opinions or point of views.

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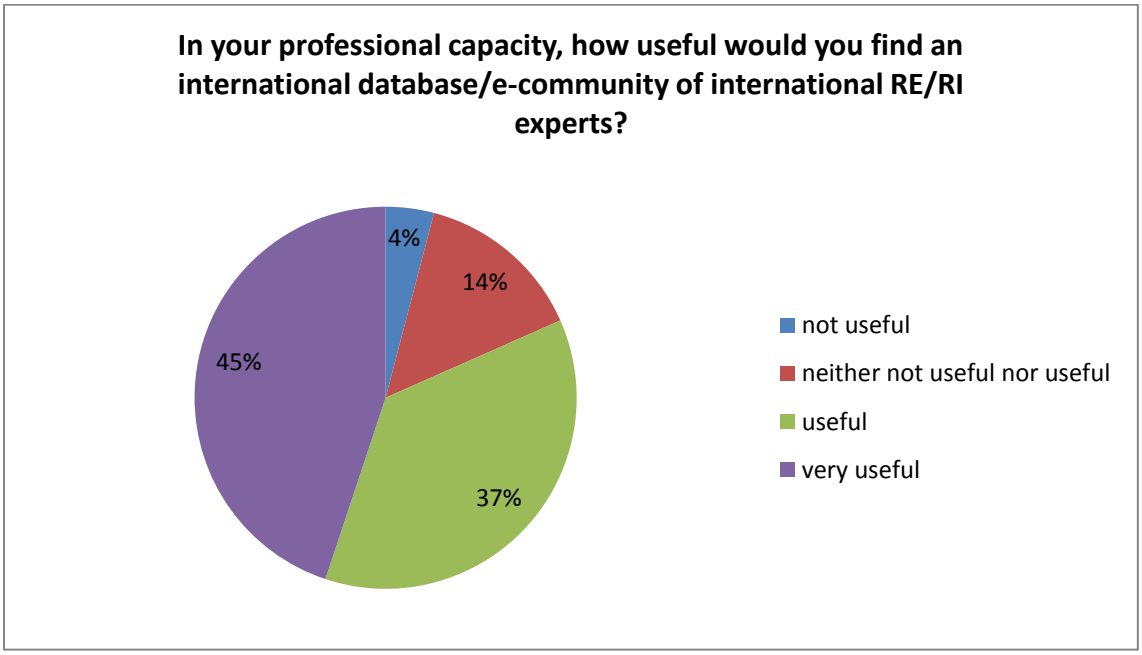
4.2. Use of database



Respondents find an international database/e-community to be a very useful initiative with 82% answering useful or very useful and only 4% saying that such a database would not be beneficial.

When asking about potential use of such a database/e-community respondents name various uses on an almost equal basis with the potential use to 'find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. (4,00) and 'find research ethics experts for European/international networks' (4,04) somewhat standing out. However respondents would find the database in looking for experts for ethics reviews (3,43), for RE/RI committees 3,28/3,70) or find expert to assist research integrity officers (3,70). Respondents would also use the database to look for experts in teaching RE/RI (3,32/3,55) or to be RE/RI speakers at conferences.

Key points:

Respondents find an international database/e-community to be a very useful initiative and name various uses from the potential use to 'find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. and 'find research ethics experts for European/international networks'.

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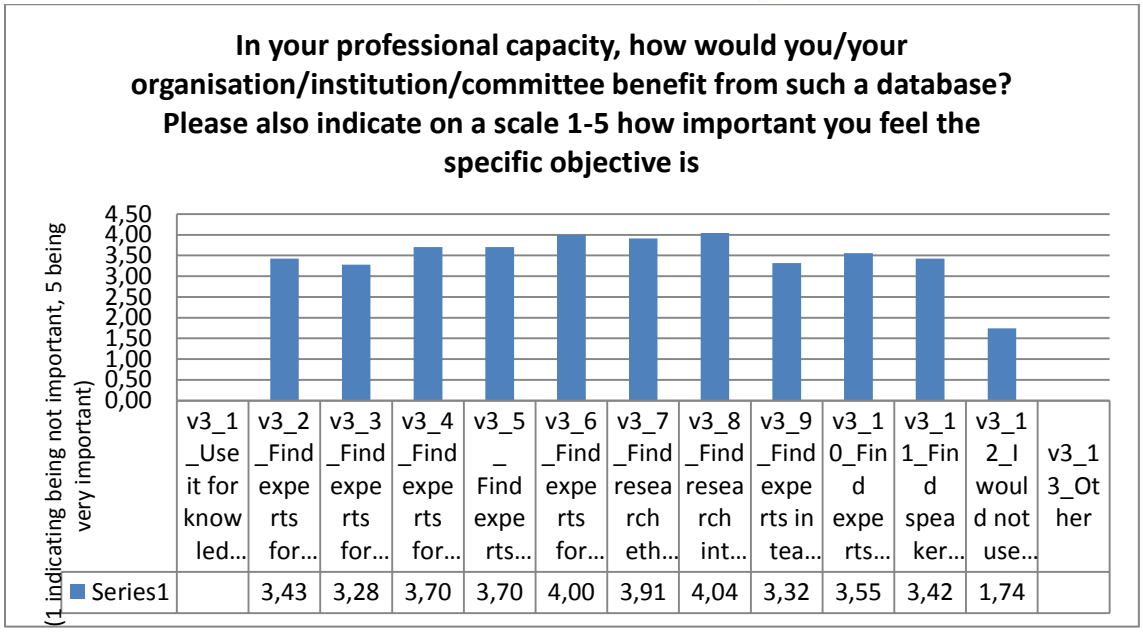

4.3. Database design

When discussing database design in light of the different skills and competences respondents suggest that the design of the database should (pre)define all skills and expertise of the database members (4,3), while they value an open and inclusive approach (or co-design) to a somewhat lesser extent (4,22). Respondents also seem to suggest that while the years of practical experience is somewhat more important than specific educational background (3,62), senior level experience is not overly important (3,63).

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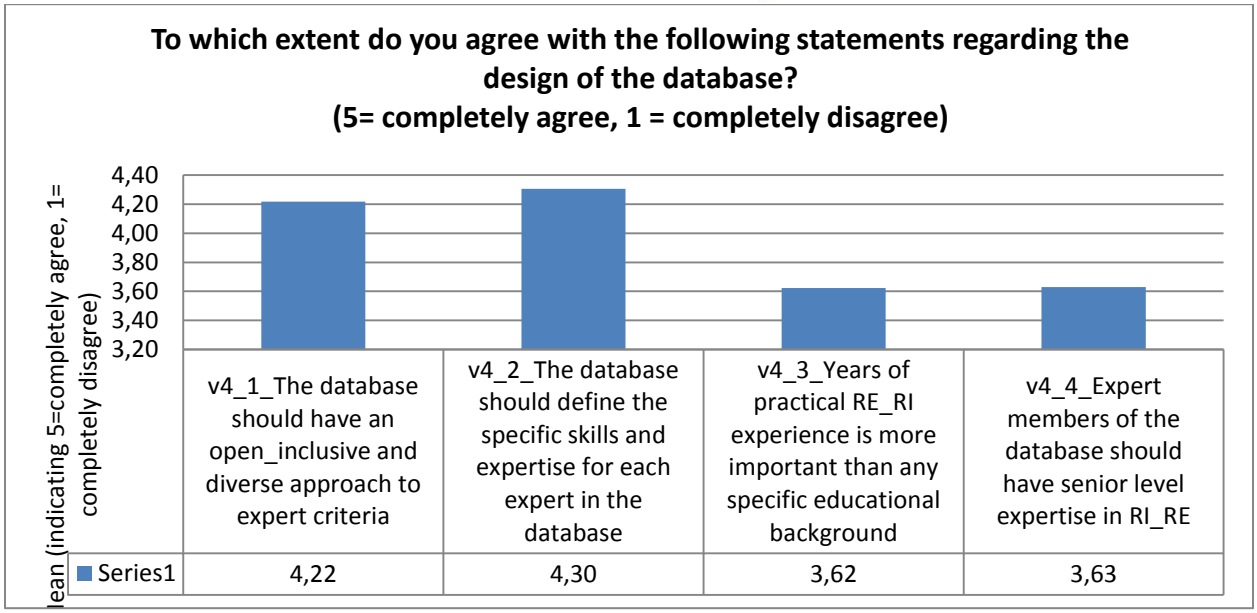
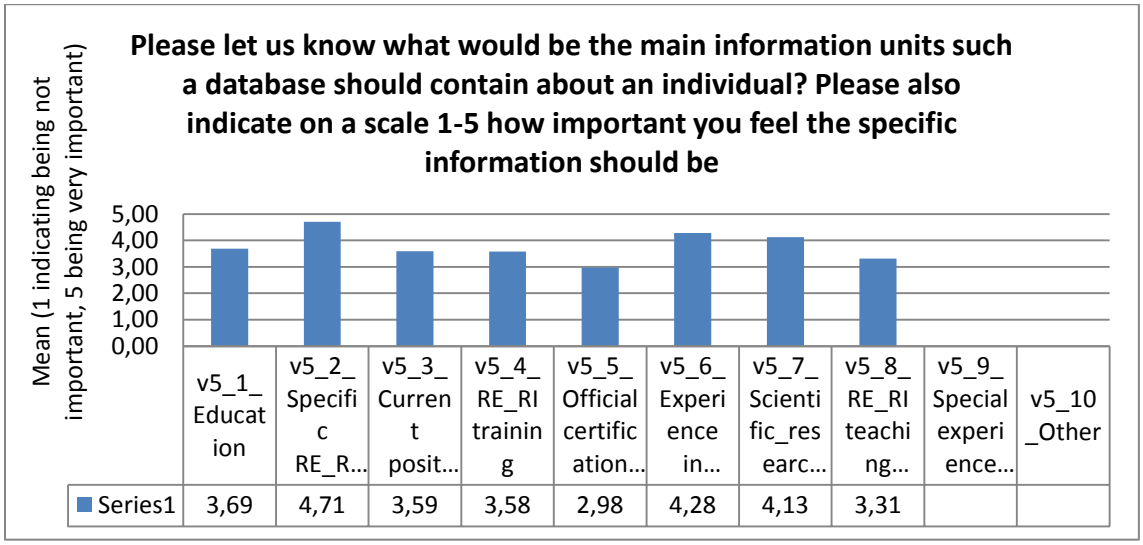


When it comes to specific skills and competences, in accordance with what has been said previously, respondents value RE/RI experience (4,71) as well as previous experience in RE/RI commissions experience (4,28) the most, closely followed by scientific/research experience (4,13). Specific education, current position as RE/RI expert or RE/RI teaching experience are all valued somewhat (3,69/3,58 and 3,31 respectively); while respondents seem to be skeptical towards the importance of an 'official RE/RI certification' system.



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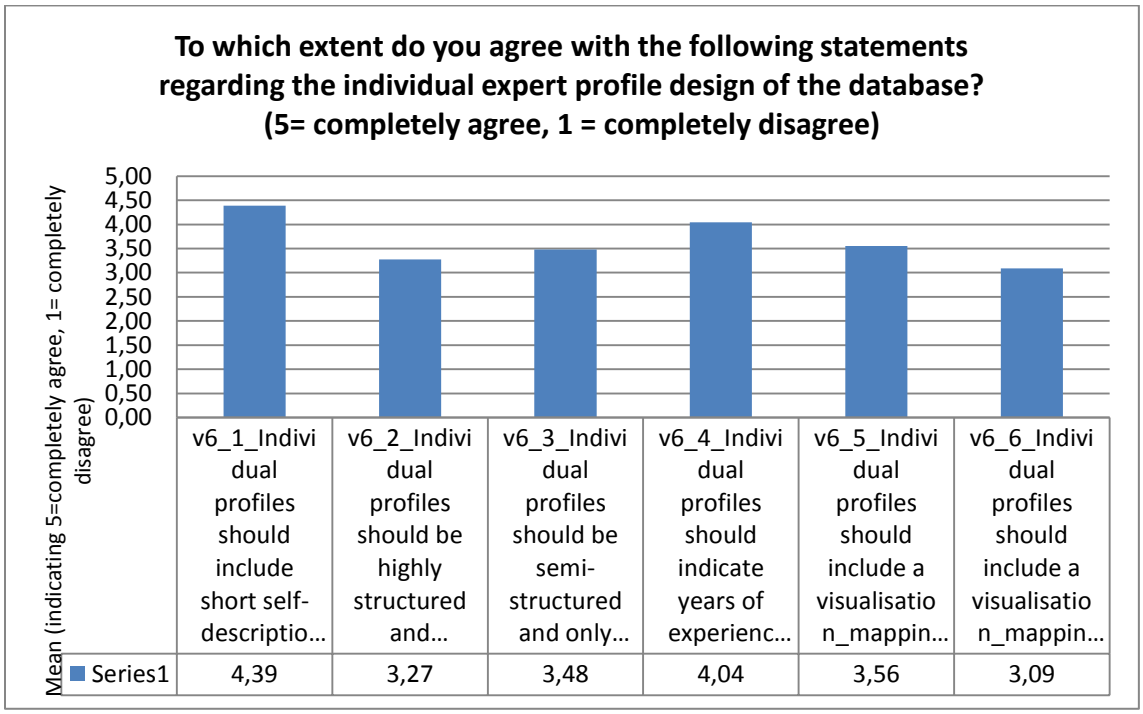
When inquiring about the structure of the database respondents value a number of short self-descriptions of key areas of expertise (4,39) over tick-off standardized categories (3,27) or a few standardized themes and open cells for filling in whatever the expert finds important (3,48); visualization of expertise or skills to acquire seem only mildly important to respondents.



As for registration of experts in the database respondents seem to be split between an open and a controlled approach to registration; while a relative majority would opt for a more controlled approach (39%). The biggest number of respondents would suggest an EU controlled registration (25%), while some respondents suggest that experts should be nominated by the relevant national bodies (14%). Open access and self-assessment is a clearly minority opinion (12%).

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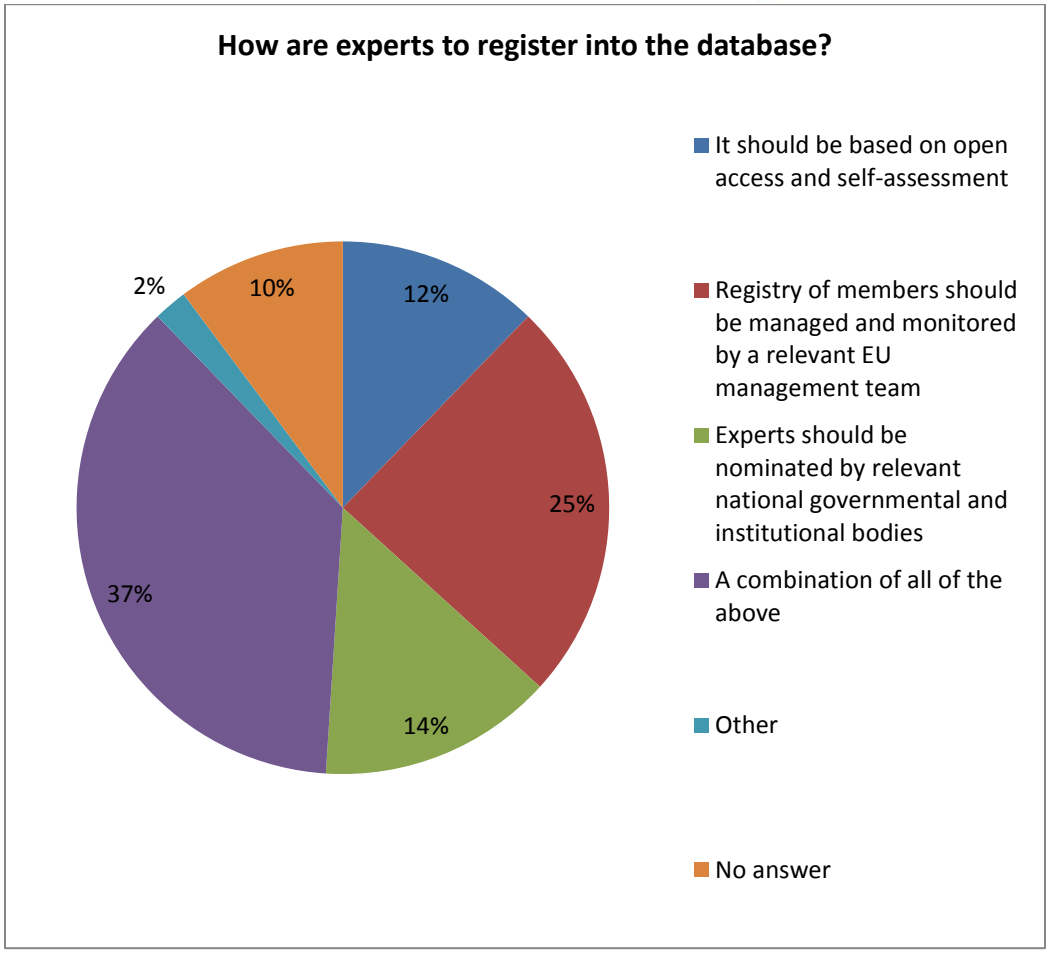

Key points:

Respondents suggest that the design of the database should (pre)define all skills and expertise of the database members as well as years of practical experience is somewhat more important than specific educational background. When it comes to specific skills and competences respondents value RE/RI experience as well as previous experience in RE/RI commissions experience the most, closely followed by scientific/research experience. As for the structure of the database respondents value a number of short self-descriptions of key areas of expertise over tick-off standardized categories or a few standardized themes and open cells for filling in whatever the expert finds important.

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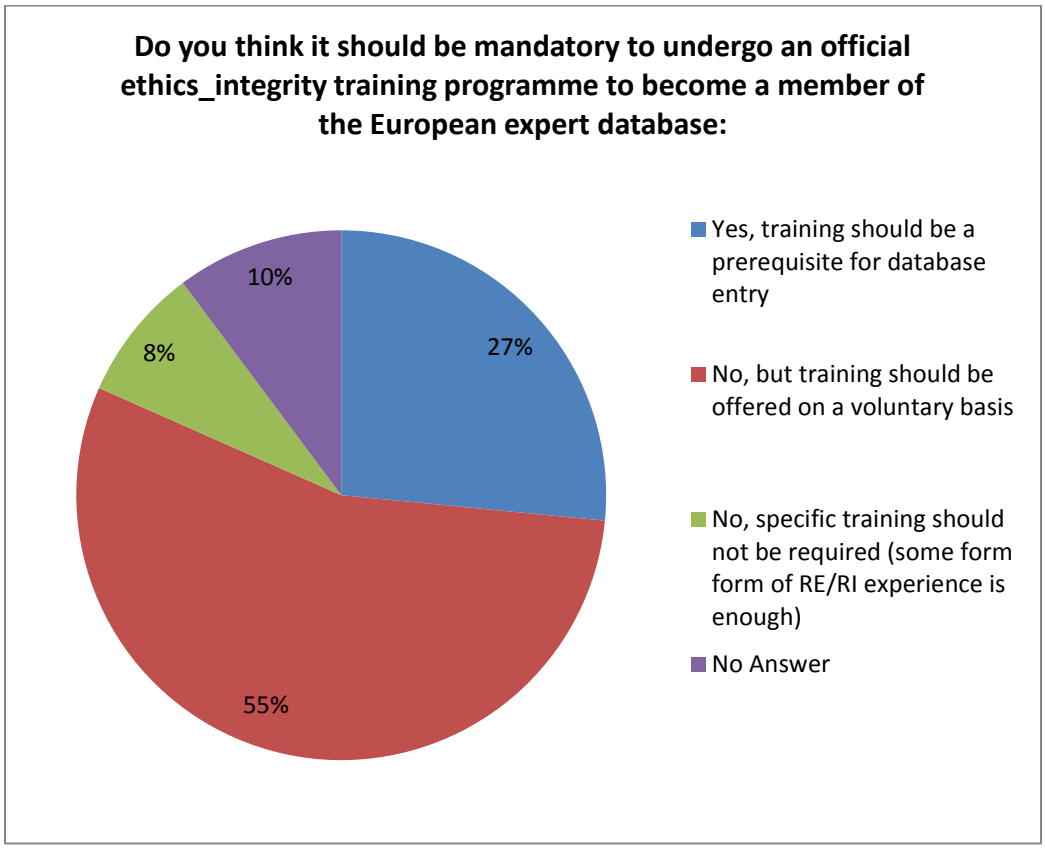
4.4. Training requirements

Consistent with previous answers on the importance of 'official training' the majority of respondents claim that training should only be offered on a voluntary basis and not be made mandatory (55%). However also slightly more than one quarter of respondents (27%) suggest that subscribing to an official RE/RI training should be a prerequisite to be entered into the database.



When discussing the kind of training required for database entry/voluntary participation, the relative majority of respondents suggest that 'any ethics/integrity training' should be accepted (36,7%) as opposed to a certified training by the database management team or other official body (28,6%). However, almost one quarter of the respondents (24,5%) do not find this issue relevant at all and would accept any solution.

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Key points:

The majority of respondents claim that training should only offered on a voluntary basis and not be made mandatory and 'any ethics/integrity training' should be accepted as opposed to a certified training by an official body.

4.5. Certification

When defining the type of certification required for the training, a majority (53,1%) would opt for a certification to be received at the end of the completion of the course as opposed to the requirement of certifying the teaching method (20,4%) or the whole course having a certification (6,1%).

Respondents are split as to whether some kind of personal certification be issued for members of the database with a somewhat higher proportion of respondents opting for no personal certification (35%) over issuing some form of certification (26%). This is consistent with the next answer, where respondents are evenly split between assuming that such certification would be an incentive to enter the database (33%) as opposed to those who think that such certification would not provide any incentive (33%).

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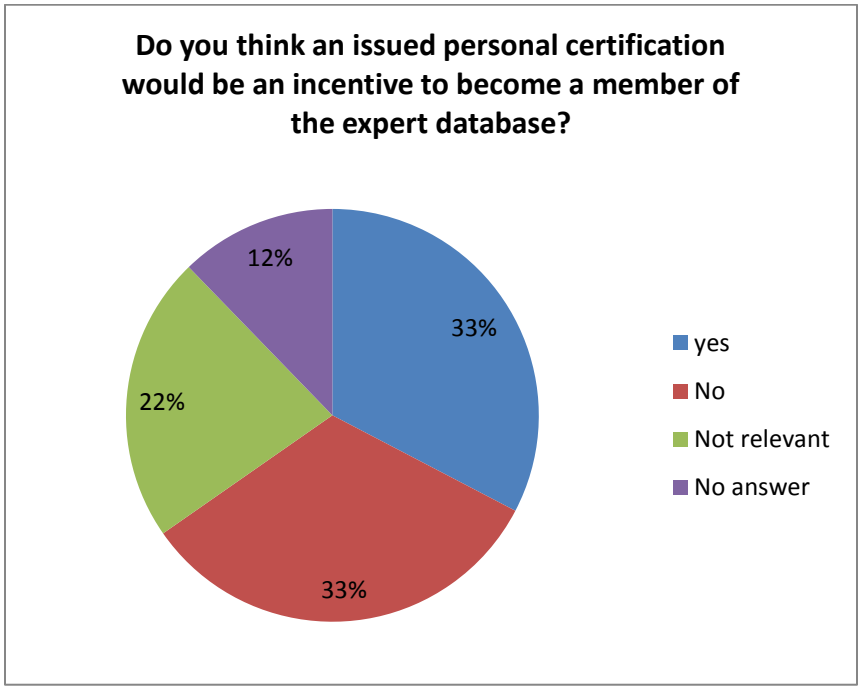
Key points:

When defining the type of certification required for the training, a majority would opt for a certification to be received at the end of the completion of the course as opposed to the requirement of certifying the teaching method.



4.6. General remarks

Respondents were also given the opportunity to add their own thoughts. Some reinforced the goal of the project as to establish a European RE/RI database claiming that "my organization would immensely profit from an international database! So my wish is just that it becomes reality..." Most open answers concern the question of certification (again: in accordance with our expert interviews). One respondent refers to the fact that "certification is not available in all EU member states therefore, it should not be a criteria" while another writes that design should focus "at people who have already done work in the field / have hands-on experience, rather than imposing training or certification".

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4.7. Conclusion

Our expert interviews represented a broad agreement among experts concerning the valuable aspect of establishing a database, adopting an inclusive, diverse and transparent approach to RE/RI expertise. This has been reinforced in the quantitative survey. As for skills and qualifications most experts explicitly suggest adopting a broad, diverse and inclusive approach to RE/RI expertise. According to experts, formal and relevant education, as well as established experience within a certain RE/RI field of expertise, counts as the most important RE/RI expert criteria. These preferences have also been confirmed by the quantitative research as survey respondents value 'experience' or praxis in RE/RI assessment the most; additionally they would like to see experts possess some theoretical ethics/philosophy (and to a lesser extent 'legal') knowledge to back up their practical experiences. Expert interviews have shown that soft skills need to feature in the individual database profiles and into the final sets of criteria/indicators in some form. Respondents in the quantitative survey have emphasized 'impartiality', and 'open mindedness' as well as 'personal commitment'. 'Administrative' and 'technical' skills are valued the least, while 'analytical', 'problem solving' and 'debate/deliberation' skills are highly valued therefore will potentially be included in the database design. Experts are in agreement with respondents in our survey that an optional training course before entering the database might be relevant, but it should not be mandatory. Experts see a personal certification as a good idea and so do respondents in the survey: a majority would opt for a certification to be received at the end of the completion of an RE/RI training course.

The project leading to this application has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 710184.

5. References

ENERI (2016): Proposal template. European Network of Research Ethics and Research Integrity.

Ravn, T. Braun, R. & Drivdal, L. (2017). Review of RI/RE expert qualifications. ENERI, WP6, 6.1., 1- 33.

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6. Further information

Questionnaire for online survey about research ethics and -integrity expertise

Prepared by: Robert Braun, Tine Ravn, Erich Griessler, Niels Mejlgaard

Introduction

Research integrity (i.e. professional standards of conducting research) and research ethics (i.e. moral principles embedded in research) are pertinent topics in scientific research. The changing nature of science and of research infrastructures together with a rising number of cases of research misconduct, have shown a continued importance for different kinds of research ethics and research integrity expertise – for instance individually represented by RE/RI practitioners, policy/law experts and academic experts or collectively in the form of RI/RE committees and assessment boards, among others.

The EU commission wishes to build an e-community/database of European and international experts in the different fields of research ethics and integrity. Such a database would assist responsible people in setting up oversight bodies, committees, teaching and training and other processes involving people with the appropriate skills, competences and experience. We would like to seek your advise on how to best design the expert database, including your assessment on relevant and core RI/RE expert skills and competences.

1. **Please let us know what are the core competences (knowledge) and skills (practical ability) you think a research ethics/research integrity expert should possess. Please also indicate on a scale 1-5 how important you feel the specific competence is (1 -- being not very important; 5 -- being very important).**

    - Ethics/philosophy competences [scale 1-5]
    - Research/science competences [scale 1-5]
    - Religious competences [scale 1-5]
    - Legal competences [scale 1-5]
    - RE/RI teaching competencies [scale 1-5]
    - Ethics assessment/review competencies [scale 1-5]
    - Integrity assessment/review competencies [scale 1-5]

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- Other (open) [scale 1-5]:

Skills (scroll down menu – you can choose more than one)

- Interpersonal [scale 1-5]
- Open-mindedness [scale 1-5]
- Administrative [scale 1-5]
- Communicational/mediational [scale 1-5]
- Impartial [scale 1-5]
- Problem solving [scale 1-5]
- Analytical [scale 1-5]
- Decision-making [scale 1-5]
- Debate/deliberation [scale 1-5]
- Personal commitment [scale 1-5]
- Co-operation [scale 1-5]
- Societal/cultural awareness [scale 1-5]
- Assessment (benefits, risks, societal challenges) [scale 1-5]
- Technical/IT [scale 1-5]

- Other (open) [scale 1-5]:

2. **In your professional capacity, how useful would you find an international database/e-community of international RE/RI experts? (1 -- being not very useful; 5 -- being very useful)**

3. **In your professional capacity, how would you/your organisation/institution/committee benefit from such a database? Please also indicate on a scale 1-5 how important you feel the specific objective is (1 -- being not very important; 5 -- being very important.**

Objectives (scroll down menu – you can choose more than one)

- Use it for knowledge exchange/mutual learning among experts [scale 1-5]
- Find experts for ethics reviews [scale 1-5]
- Find experts for research ethics committees (RECs) [scale 1-5]
- Find experts for research integrity committees [scale 1-5]
- Find experts to assist research integrity officers (RIOs) [scale 1-5]
- Find experts for guidance on RE/RI policies, guidelines, codes of conduct etc. [scale 1-5]

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- Find research ethics experts for European/international networks [scale 1-5]
- Find research integrity experts for European/international networks [scale 1-5]
- Find experts in teaching research ethics [scale 1-5]
- Find experts in teaching research integrity [scale 1-5]

Other (open) [scale 1-5]:

- I would not use such a database

4. **To which extent do you agree with the following statements regarding the design of the database?**

	Completely agree	Partly agree	Neither agree nor disagree	Partly disagree	Completely disagree
The database should have an open, inclusive and diverse approach to expert criteria					
The database should define the specific skills and expertise for each expert in the database					
Years of practical RE/RI experience is more important than any specific educational background					
Expert members of the database should have senior expertise					

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5. **Please let us know what would be the main information units such a database should contain about an individual? Please also indicate on a scale 1-5 how important you feel the specific information should be (1 -- being the not important; 5 -- being very important)**

   - Education [scale 1-5]
   - Specific RE/RI expertise [scale 1-5]
   - Current position at employing institution [scale 1-5]
   - Ethics/integrity training [scale 1-5]
   - Certification [scale 1-5]
   - Experience in ethics/integrity commissions [scale 1-5]
   - Scientific/research experience [scale 1-5]
   - RE/RI teaching experience
   - Special experience [scale 1-5] – please specify _____

   - Other [scale 1-5]:

6. **To which extent do you agree with the following statements regarding the individual expert profile design of the database?**

	Completely agree	Partly agree	Neither agree nor disagree	Partly disagree	Completely disagree
Individual profiles should include short self-descriptions of key areas of expertise					
Individual profiles should be highly structured and include a large number of 'tick-off' standardised categories					
Individual profiles should be semi-structured and only include few predefined key areas/themes of expertise + open categories					

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Individual profiles should indicate years of experience within particular areas of expertise					
Individual profiles should include a visualisation/mapping of key competencies/skills					
Individual profiles should include a visualisation/mapping of potential capacities for skill development					

7. **How are experts to register into the database?**

    a. It should be based on open access and self-assessment
    b. Registry of members should be managed and monitored by a relevant EU management team
    c. Experts should be nominated by relevant national governmental and institutional bodies
    d. Other, please specify: _____

The next questions concern possible training requirements to get into the expert database:

8. **Do you think it should be mandatory to undergo an 'official' ethics/integrity training programme to become a member of the European expert database?**
    a. Yes, training should be a prerequisite for database entry
    b. No, but training should be offered on a voluntary basis
    c. No, specific training should not be required (some form of experience is enough)

9. **If training is required do you think that only certified ethics/integrity training should be accepted?**
    a. Yes, only certified trainings should be accepted

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b. No, any ethics/integrity training should be accepted
c. Not relevant

10. **If certification of ethics training is required, do you think the certification should be based on:**
    a. The process/method applied
    b. The full training must have a certification
    c. The individual should receive a certification on completion

The next questions concern the issue of expertise certification:

11. **Do you think that a personal certification should be issued and required as a member of the expert database**?
    a. Yes
    b. No
    c. Not relevant

12. **Do you think an issued personal certification would be an incentive to become a member of the expert database?**
    a. Yes
    b. No
    c. Not relevant

13. **If you have any further comments regarding relevant research ethics/research integrity skills and qualifications, please state them below.**

14. **If you have any further recommendations on how to design the expert database, please state them below**

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Thank you very much for answering the questionnaire!

On behalf of The Institute for Advanced Studies, Vienna; the Danish Centre for Studies in Research and Research Policy, Aarhus University and the ENERI consortium

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